EXHIBIT B

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION :

PATRICIA HAMMONS, : MAY TERM, 2013
Plaintiff:

v. :

ETHICON, INC., et al., :
Defendants : NO. 3913

- - -

Monday, December 7, 2015

- - -

COURTROOM 246
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J.,
and a Jury
- - -

JURY TRIAL VOLUME V

AFTERNOON SESSION

REPORTED BY:
JUDITH ANN ROMANO, CM, CRR
CERTIFIED MERIT REPORTER
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

A P P E A R A N C E S:

KLINE & SPECTER, A Professional Corporation
BY: SHANIN SPECTER, ESQUIRE
BY: KILA B. BALDWIN, J.D., ESQUIRE
1525 Locust Street
The Nineteenth Floor
Philadelphia, Pennsylvania 19102
T: 215-772-1000 F: 215-735-0937
E-mail: shanin.specter@klinespecter.com
kila.baldwin@klinespecter.com
Counsel for Plaintiff Hammons

MAZIE, SLATER, KATZ & FREEMAN
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
T: 973-228-0454 F: 973-228-0303
E-mail: aslater@mskf.net
Counsel for Plaintiff Hammons

DRINKER BIDDLE & REATH, LLP
BY: MOLLY E. FLYNN, ESQUIRE
One Logan Square, Suite 2000
Philadelphia, Pennsylvania 19103-6996
T: 215-988-2836 F: 215-988-2757
E-mail: molly.flynn@dbr.com
Counsel for Defendants Ethicon and Johnson and Johnson

TUCKER ELLIS, LLP
BY: MATTHEW P. MORIARTY, ESQUIRE
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113-7213
T: 216-696-2276 F: 216-592-5009
E-mail: matthew.moriarty@tuckerellis.com
Counsel for Defendants Ethicon and Johnson and Johnson

A P P E A R A N C E S: (Continued)

GOLDMAN, ISMAIL, TOMASELLI, BRENNAN & BAUM, LLP
BY: TAREK ISMAIL, ESQUIRE
(admitted pro hac vice)
564 West Randolph Street, Suite 400
Chicago, Illinois 60661
T: 312-681-6000 F: 312-881-5190
E-mail: tismail@goldmanismail.com
Counsel for Defendants Ethicon and Johnson and Johnson

THOMAS COMBS & SPANN, PLLC
BY: SUSAN M. ROBINSON, ESQUIRE
(admitted pro hac vice)
300 Summers Street, Suite 1380
Charlestown, WV 25338
T: 304-414-1800 F: 304-414-1801
Counsel for Defendants Ethicon and Johnson and Johnson

- I N D E X -

Q To give increased patient comfort, right?
A That's what this is stating.
Q You talked a little bit with counsel about some clinical evidence about what would happen when mesh had to be removed? Remember you mentioned that?
A I think we had a couple of discussions about that.
Q Do you have the Clinical Expert Report handy, that report document that we have been talking about for a couple of days?
A I have a version of it. I don't know that I have the final signed version here.
Q You do. It's Exhibit P2137. Do you remember counsel asked you to look at it?
A I am holding P680. I don't know if it's the same thing.
MR. SLATER: Your Honor, to save time should I approach?
THE COURT: You can pass up whatever you like.
MR. SLATER: I don't have another copy.
THE WITNESS: I am sorry 2137? It found its way up.

Q So you had clinical evidence about the very critical question of what would happen when mesh had to be removed from a woman's body due to complications. That's what you told counsel, right?
A I don't know that we had specific clinical evidence. I said that I think the only way you would be able to evaluate that is through an evaluation of complications from that clinical data. That's really the only thing I can imagine.
Q So we are back to the starting point we were at Friday, which is it's a question you did not look at to your knowledge, is that right?
A I am sure Medical Affairs would have looked at all the complications.
Q You have no knowledge that they did, you have no evidence of it as you sit here now, right?
MS. ISMAIL: Objection, Your Honor.
THE COURT: Objection sustained.
That's two questions.
Q You have no evidence as you sit here now that Medical Affairs actually evaluated that question, right?
A I didn't sit in a room and watch them look at that specifically, no.

Q And in this Clinical Expert Report, that key paragraph "Clinical Evidence," where you said you were looking for more than a blank space? Do you remember that?
A Yes, I do.
Q Does it talk about removal of mesh and what can happen when you remove mesh?
MS. ISMAIL: Objection, Your Honor, repetitious.
THE COURT: Overruled.
A I don't think it speaks there specifically. One of those articles referenced it we may have talked about.
THE COURT: Wait a minute, the question doesn't talk about it. Does it talk about it?
THE WITNESS: No, she is just referencing different studies.
THE COURT: So it doesn't talk about it, right?
THE WITNESS: Yes, correct.
THE COURT: Anything further?
MR. SLATER: Just checking my notes, Your Honor, I am almost done, I think.
(Pause.)

MR. SLATER: No other questions, Your Honor.
THE COURT: Is anything further?
MS. ISMAIL: There is not, Your Honor, thank you.
THE COURT: You may step down.
- - -
(The witness is excused.)
- - -
THE COURT: Next witness.
MR. SLATER: Your Honor, if we can have Five minutes just to make the transition, it would be helpful.
THE COURT: We will take ten minutes.
(A brief recess is taken.)
- - -
(The following transpired in open court.)
THE COURT: We are on Witness Weber.
MR. SLATER: Yes, Your Honor.
THE COURT: Is that Dr. Weber?
MR. SLATER: Yes, Your Honor.
THE COURT: And Dr. Weber prepared a several-hundred page report, is that correct?

MR. SLATER: Multiple reports, her initial report was 520 pages.

THE COURT: I will take an offer of proof.

MR. SLATER: The testimony we will provide will not, for the most part, overlap. It will be her qualifications, her materials reviewed, she will touch base on alternative options being viable and safe --

THE COURT: Counsel, what will her testimony be?

MR. SLATER: That is what I am saying.

THE COURT: No, you told me she will touch base on something. I don't want topics, I want an offer of proof.

MR. SLATER: I am just concerned, Your Honor, about laying out my whole direct for the defense right now.

THE COURT: If you don't want to give me an offer of proof you don't have to, but it may make their motion to preclude pretty easy.

MR. SLATER: She is going to offer the opinion that there were safer alternatives available at the time, and she is an expert

with regard to most of them -- with regard to all of them.

THE COURT: Anything else?

MR. SLATER: She is going to speak briefly about Ultrapro in the Prolift+M and testify that would have been a safer alternative.

As a matter of foundation, I will be going through an Ethicon report on mesh erosions and laying a foundation and asking her opinions on the significance of various passages in an Ethicon document she has relied on. I will be doing that with regard to two documents. I will then be taking her through the actual studies that we have been hearing about in this trial, the Gynemesh PS study, the TVM studies, and she will be going through -- she actually reviewed all of the case report forms in those studies, the actual patient level data, the protocols, the reports, and did her own independent analysis, and she will be showing the jury the data that she found based on her independent analysis.

THE COURT: Which will be what?

MR. SLATER: I would have to pull the exhibits out. There is charts on findings of recurrence rate --

THE COURT: Can it be summarized?

MR. SLATER: In part, for example, a 20.7 percent exposure rate at one year in the French study, and she will also be pointing out that the recurrences in the U.S. study were undercounted, so that study also failed the endpoint.

THE COURT: Anything else?

MR. SLATER: Yes. Those are examples, that's not complete, but her opinions on the review of the data has to do with recurrences and exposures/erosions, and the overall benefit-risk profile shown by these studies.

In the context of the Gynemesh PS study, she will be shown pages from the professional education deck that was in use when Dr. Baker was trained and there will be information in that about the Gynemesh PS study which she will point out is incorrect. And there is one other page in there about the recurrence rates with other procedures and she

will simply opine those are incorrect rates.

She is familiar with all the literature that is cited.

She will then go through a database of data from Vince Lucente, the surgeon we heard about during the trial. Through subpoenas we were able to get his, what's called an Investigator Initiated Study database. Dr. Lucente got funding from Ethicon to evaluate his own patients, and it was over 500 patients. Dr. Weber actually went through all of the data and evaluated it and came up with what his erosion rates, recurrence rates, and reoperation rates were and will compare those to what was represented in a public abstract and other publications by him, to point out that the complications when we finally got his own internal data were far worse and far higher than anything he had ever published before.

And that's all data that's been relied upon by Ethicon, and in fact, he was one of the study investigators in both the Gynemesh PS and TVM studies, and we learned that he had

some inconsistencies in how he recorded data, and that will be probably referenced.

Time permitting, depending on how fast we move, we have two PowerPoints from those design control processes, where Dr. Weber has just listed medically, medical harms that were not evaluated in that design control process.

She will offer an opinion on the Clinical Expert Report that it did not validly evaluate the safety and efficacy. I will not walk through it at all, I will simply ask if she is familiar with it and her opinion. She has a foundation of knowing all of this, I will not go through any of what we already heard.

She will talk about a particular study by Dr. Lowman, the defense expert on dyspareunia which they are relying on and had in their opening PowerPoint, and she will point out that the data reported is misleading and explain why. That's my word "misleading". She will show the true dyspareunia rates based on the data that's available in those studies. Counsel had a 16 percent rate on the board, we

will show it as high as 39 percent based on the data available.

She will then be shown the abstract of a presentation by the TVM group in 2005, where they characterized the 6.7 percent erosion rate as high. A subsequent article on the same group of 687 patients, where they had an 11.3 percent erosion rate in 3.6 months and a 33.6 percent complication rate at that time and characterized this as a relatively high incidence of post-surgical complications. She will obviously have opinions as she goes through this, but we are going to walk through literature.

Then we are going to go through a poster presentation by the Ethicon TVM group, where they said they needed to study the procedure further before they would recommend that it be used in young women or for primary prolapse repair, and she will be in agreement with that, that they needed much more study.

She will look through a PowerPoint on the TVM group presentation, where they said it actually should be placed in women with stage

three or four symptomatic prolapse where it's actually causing symptoms. She will then be asked about another article by the TVM group where they did ultrasound evaluations of the Prolift and show that 89 percent of the women had moderate to severe mesh retraction shown on ultrasound with significant increase in the thickness of the mesh, and then go to a presentation by the same doctors where with those patients they showed that 19.6 percent of those women had painful vaginal examinations due to mess contraction.

She will authenticate an article by an author named Diwadkar, and point out that the dyspareunia rate in a meta-analysis was shown for suture repairs to be only 1.5 percent with a reoperation rate lower than with mesh.

And finally, she will talk about the ACOG, American College of Obstetricians and Gynecologists, February 2007 practice bulletin, which she authored, so I will intend to display it to the jury, and the primary thing I am going to show the jury is that she opined in that that this procedure should be

deemed experimental, these tissue mesh kit procedures should be experimental. And then I am going to bring out that that was changed later that year by ACOG and they took the word "experimental" out, and then what I intend to do is display the letter she wrote to the editor of the *International Urogynecology Journal* on August 8, 2009, where she took issue with the change and expressed her views on why that was wrong and why this should remain experimental. And I intend to have her -- it's a one-page letter -- to literally read it to the jury because that is the full synopsis of the opinions she formed and they were all formed before she ever spoke to counsel.

And that will be, I believe, other than asking her a few questions about the risk-benefit profile not being acceptable based on the literature and the studies she's talked about, that will be the end of her testimony.

THE COURT: So what if anything is she unqualified for?

MS. ROBINSON: Your Honor, Dr. Weber hasn't practiced medicine since the year of 2005. She hasn't been licensed since 2007. The last time she performed a surgery was in --

THE COURT: Speak a little louder.

MS. ROBINSON: The last time she performed surgery was 2004, prior to Prolift even coming on market. She has never implanted a Prolift, she has never seen a patient who had a Prolift, she never addressed complications with anybody involving Prolift. She is simply unqualified to opine on Prolift and its risk/safety profile, and she is unqualified to opine on causation factors related to this particular plaintiff.

THE COURT: I didn't hear anything about that. Is she going to testify about this particular plaintiff and causation factors?

MR. SLATER: I do not intend to elicit any opinions specific to the plaintiff.

THE COURT: She is not going to testify to that. Any other reasons why she is

unqualified?

MS. ROBINSON: She is unqualified to testify about the education that doctors undergo to implant Prolift and the proper way to do that and the proper way to teach that.

THE COURT: Did you say that?

MR. SLATER: The only thing I said is I am going to --

THE COURT: Did you say that?

MR. SLATER: I did not say that. I am not going to ask that question.

THE COURT: I don't understand, was that a waste of time or --

MS. ROBINSON: He was talking about Dr. Baker's education, the professional education that was provided to Dr. Baker. I understood that she was --

THE COURT: She is not qualified to testify about the professional education provided to Dr. Baker? Is that it? What is ACOG?

MS. ROBINSON: The first part about ACOG --

THE COURT: What is it?

MS. ROBINSON: ACOG is the American College of Obstetrics and Gynecology.

THE COURT: Did she write something on their behalf on this topic?

MS. ROBINSON: She wrote a bulletin regarding prolapse.

THE COURT: Did they publish that bulletin?

MS. ROBINSON: It was published, yes.

THE COURT: Was she qualified at that time? Did ACOG consider her qualified to publish that bulletin across the country for doctors to read?

MS. ROBINSON: With regard to the condition of prolapse, yes, Your Honor. But the second point I want to add about ACOG is that we have already heard from Dan Elliott, Dr. Elliott, who has testified about ACOG, testified exactly as to what counsel had just indicated, which was there was a word "experimental" put in the ACOG bulletin, it was removed, and he testified about that process. So that's already been covered.

He testified at length about mesh

contracture and I believe the particular study that she is going to talk about. He testified at length about contracture, the risk-benefit safety profile. He testified about the TVM study and that it failed its primary endpoint. He testified about safer alternatives, and he testified about physician education.

THE COURT: Your objection is overruled. Are we ready to bring the jury in?

MR. SLATER: Your Honor, I am going to need a couple of minutes to set up.

THE COURT: I am sorry, did you leave something out?

MS. ROBINSON: Yes. There was one specific objection concerning the Lucente database that counsel mentioned. The witness has gone through a database that was acquired by subpoena through a third party, that being Mr. Lucente and his practice group. There is no evidence that that database is a final database, that it had been vetted, that all of the patients had been seen and their information reported in that database. In fact, the testimony --

THE COURT: You mean the database itself would be impermissible?

MS. ROBINSON: Yes.

THE COURT: An expert is entitled to rely on things otherwise impermissible in evidence. So that objection is overruled as well.

(A brief recess is taken.)

(The jury enters the courtroom at 3:37 p.m.)

THE COURT: Counsel, your next witness.

MR. SLATER: Thank you very much, Your Honor. The Plaintiff calls Dr. Anne Weber.

- - -

(ANNE MARGARET WEBER, M.D., is duly sworn.)

THE COURT: Please be seated. I understand you have some medical condition if you would prefer to stand.

THE WITNESS: I would prefer to stand.

- - -

DIRECT EXAMINATION (Qualifications)

- - -

BY MR. SLATER:

Q Good afternoon, Dr. Weber.

A Good afternoon.

Q I would ask you as best you can to keep your voice up and project so the jury hears what you have to say, okay?

A Yes.

Q Please tell the jury just for the record what your name is and where you live?

A My name is Anne Margaret Weber, and I live in Baltimore, Maryland.

Q We have put in front of you something that we have marked as Exhibit 3384. What is that?

A This is my CV.

Q What does that mean? What's in there?

A So in professional life you make a record of your experiences, education in the medical field, if you are in academics, the articles you have written, presentations you have given, honors received, and so on.

Q If you need to refer to it you are certainly welcome to, I am going to ask you some questions about that now, okay?

A Yes.

Q Please tell the jury about your educational

background, where did you go to college, take us through medical school?

A I graduated from college at the University of Maryland in College Park, and then I went to medical school also at University of Maryland, which is in Baltimore.

Q And what years are we talking about?

A I graduated from college in 1983 and then medical school in 1988.

Q And after you went to medical school, take the jury through where you went and what you did and what years, please?

A After graduating from medical school, I went to an obstetrics and gynecology residency in Hartford, Connecticut that was four years long, and after that I completed a one-year fellowship in advanced pelvic surgery at the Cleveland Clinic in Ohio.

Q What is a residency, just very briefly?

A So a residency is training in the specific field that you have chosen. So that involves care, in my field obstetrics and gynecology, in all the phases of caring for women throughout their lives, during pregnancy and childbirth and afterwards, and

then as they age, and what turned out to be my specialty, caring for women with pelvic floor disorders.

Q You did a fellowship you said at the Cleveland Clinic in advanced pelvic surgery. First, what is the Cleveland Clinic?

A The Cleveland Clinic is what's called a tertiary referral clinic. We also provided primary care to people in the community of Cleveland, but we also served as a resource to people who had more complicated problems, where they may have exhausted the resources in their local community and have a problem that needed to be addressed by people who specialized in that kind of care.

Q How large is the Cleveland Clinic?

A Large. At the time I was there, it had over 10,000 employees with an adjoining hospital that had 400 beds.

Q You said your fellowship was in advanced pelvic surgery. What specifically does that mean?

A After I graduated from residency, I decided that to really become as proficient as I felt I needed to be in performing surgery, I wanted an extra level of training. So the fellowship in

advanced pelvic surgery provided four months of training in oncologic surgery, which is the kind of surgery that women have to go through if they have cancer, reproductive endocrinology, which is for women who have hormonal or infertility problems, and that focused on laparoscopic surgery, and then the remaining four months is spent in the section of the department that cared for women with pelvic floor disorders. So surgical treatments or prolapse and urinary incontinence.

Q And when you finished your fellowship in 1993 did you join the staff in the Department of Obstetrics and Gynecology at Cleveland Clinic?

A Yes.

Q What did that mean, now that you are on the staff at the Cleveland Clinic in the OB-GYN department, what did your practice become?

A So I was focused solely on gynecology. I actually had never practiced obstetrics despite going through all of that training.

In my practice of gynecology, at the beginning I was seeing women for all kinds of problems, abnormal bleeding, fibroids, menopause, and also to a certain degree, pelvic floor

disorders, but at that early point in my career that wasn't a focal point. So I had an office practice where I was seeing women in an office setting, and then also surgery.

Q Tell us how your practice evolved going forward from 1993 onward?

A So in the same way I had chosen to do a fellowship in advanced pelvic surgery, after a few years in practice I decided that I wanted to focus exclusively on women with pelvic floor disorders. So with the support of my chairman, we changed my office practice so that I would concentrate on seeing women with those kind of problems, and well-woman care or other kinds of problems would be seen by the other gynecologists in the department.

Q And when you talk about pelvic floor disorders, very generally, what does that mean?

A So as I mentioned earlier, prolapse, which I know you have heard quite a bit about already, urinary incontinence, bowel problems. I also interacted extensively with my colleagues in urology if this was a more complicated problem than just straightforward urinary incontinence, for example, and my colleagues in the colorectal department for

women who had problems in the bowel area.

Q Doctor, in your time at the Cleveland Clinic did you have teaching responsibilities in the fellowship program?

A Yes.

Q What does that mean?

A So at the time I completed the fellowship which was only one year, we continued on that for several more years. So the fellows would come, just as I had, to advance their surgical training, and I was involved with them in the office, they would come with me as I saw patients, and then they would also be with me in surgery, where with my close supervision they were being taught, or I taught them how to perform these kinds of surgeries.

They also had a research component to their fellowship, so I also contracted with them in developing their ideas, designing a research project and carrying it out.

Q Were you Board certified?

A Yes.

Q By what board?

A The American Board of Obstetrics and Gynecology.

Q And we have heard about what that means so I am not going to take you through it.

You were the Director of Clinical Research in the Department of Obstetrics and Gynecology, what does that mean?

A Yes. So my chairman developed that role for me after I completed a graduate program at the University of Michigan. Another decision I made in my career was that I wanted to focus on research, and I felt that to really be able to design and perform the research at the highest quality, I needed more training than I had in my residency and even in my fellowship. So I decided to attend a program at the University of Michigan that was three years long, and after that I received a masters degree in clinical research design and statistical analysis.

So with that extra training and experience, my chairman created this role as Director of Clinical Research in the department so that I could bring my expertise to assist the other faculty members, fellows, residents, medical students, so that I could also enrich their research activities as well.

Q What does clinical research design and statistical analysis encompass? What does that mean that you got a masters degree in that field?

A So that really provided me with a very strong foundation in all of the different kinds of study designs, from observational studies, where you just observe people over time and see what happens to them, and all the way up to randomized trials, that I know you probably heard a bit about, but the only kind of trial where you can actually draw a conclusion about cause and effect, where -- none of the other study designs allow you to do that, there are just too many variables around that you don't have a way of controlling. But in a randomized trial the two groups are developed in a way that they should be comparable. And so when you get to the end of the study, if everybody was equal at the start, then differences in the two groups at the end, you should be able to say, okay, this group got Treatment A and this is how they turned out and this group got Treatment B and this is how they turned out. So we can say, okay, Treatment A did this compared to Treatment B. And that's the only study design where you can do that.

So I received training in designing those studies, statistical analysis as well, so that I could understand what were the appropriate tests to perform when -- first of all, in setting up the study, to set up correctly, and in the end in analyzing the data to be sure that the data were being represented accurately and in a way that people could read and understand how this meant and how significant it would be.

Q Okay. In 1999 you became involved with the National Institutes of Health, correct?

A Yes.

Q Please tell the jury, what is the National Institutes of Health, and then we will talk about your involvement.

A So the National Institutes of Health is a branch of the government that funds research around the country, and actually around the world. They also have their own research establishment in Bethesda, Maryland, and they grant money to investigators at universities to perform their own research projects.

Q And how did you become involved with the National Institutes of Health, what happened?

A So the leaders in the field of urogynecology, which is what we call the specialty that takes care of women with pelvic floor disorders, realized that the research that had previously been done in the field wasn't as strong as it could be and wasn't the kind of research that was really helping us decide what is the best way to take care of women with these problems. So they had a meeting with the leaders at NIH and discussed what could be done, and the NIH decided to create a new program that would provide a boost of research funds to investigators to start researching the problems of female pelvic floor disorders.

And so I applied for that job, and with my additional training and education in research, that's not something that a lot of gynecologists have, and so I was hired for that job.

Q And what was your title?

A I was the Project Officer for the Female Pelvic Floor Disorders unit.

Q And were you the first one to hold that position?

A Yes.

Q And what did you have to do in that role, in

general terms, I don't want to go all day on it. It's important to just give the jury a sense of what you had to do in that position as the first program director?

A As I mentioned, the general idea was to infuse a boost of research funds into the academic community. So we had several initiatives where researchers were invited to submit applications and we set aside money that would be devoted to the best applications in that group. And I also developed a network of institutions -- this was also competitive. They submitted applications and an independent group scored the applications to see which were best, and then a group of seven institutions and another institution that managed the data were selected to design and perform trials across the country.

It just makes it so much easier when you have a group of people working on the same problem than just single investigators at their own institution who will have as many patients as they have, but you can see if you expanded that by seven times and you had all these bright brains together designing these studies and getting patients

enrolled in these studies, it was possible to do research at a very high caliber and accomplish it more quickly.

Q In your CV I saw a reference to called something called the standardization of terminology for pelvic floor disorders. What does that mean and what was your involvement with that?

A So as I mentioned, there had come a realization that the research in urogynecology was not as robust as it could be and should be, and part of the problem was that doctors were just using different words to describe the same things, but when you write that down in a paper it becomes very hard to be able to say, Well, Dr. X said this and Dr. Y said that, are they saying the same things or different things.

So I decided that it would be fruitful to hold a meeting, a two-day meeting with scientists around the world and sit everybody down to come up with a set of terms that everybody could use so everyone is speaking the same language, basically. And then I authored a report, which is what Mr. Slater is referring to, to publish that in the literature so that everybody could see that and

begin to use the same language.

Q I have seen in your CV that you have published articles in the peer-reviewed literature. You have just alluded to that?

A Yes.

Q I see about a hundred or so in here?

A Yes.

Q Just very briefly, what does it mean for you to publish an article in peer-reviewed literature?

A So the literature that Mr. Slater is referring to is published in professional journals. Every medical scientific branch has their own set of journals that researchers publish in, and the meaning of peer reviewed is that once an author or a scientist submits an article to that journal, it's then reviewed by peers, which are other scientists who then judge the article, decide if the science is robust, if the results have been recorded well, and decide if that would make a contribution to the literature overall.

Q Have you yourself acted as a peer reviewer?

A Yes.

Q Can you estimate the number of journals you acted as a peer reviewer over the years?

A In my busiest time in my academic career I would say 15.

Q As a peer reviewer what were you doing?

A I would receive the manuscript that other authors had submitted to this journal in particular, I would receive that and then be asked to review the manuscript and judge its quality, whether the methods were strong enough to actually answer the question that had been posed, whether the results had been analyzed and recorded, and how reliable was that conclusion going to be. And then I would make my comments, which are sent back to the editor, with other reviewers, and then feedback goes to the authors.

Q Are you currently acting as a peer reviewer?

A Yes.

Q For what journal?

A The *British Journal of Obstetrics and Gynecology, the American Journal of Obstetrics and Gynecology* and the *International Urogynecology Journal.*

Q What I would like to do as part of going through your background, what I have handed you is --

THE COURT: Counsel, didn't you say she had written 200 or so peer-reviewed articles?

MR. SLATER: I think it was about a hundred peer-reviewed articles.

THE COURT: Do you intend to ask her about every one on qualifications?

MR. SLATER: I absolutely do not.

THE COURT: Are you going to ask her about any?

MR. SLATER: This one.

THE COURT: Why?

MR. SLATER: I think it's an important article in the medical literature in this field.

THE COURT: Then she can talk about it if she is qualified to provide testimony. Proceed.

BY MR. SLATER:

Q Putting the article down, in the course of the studies that you performed and the articles that you have written, did you perform a randomized control trial comparing suture-type procedures with mesh procedures?

A Yes.

Q Had there ever been a randomized control trial addressing that question?

A No.

Q And that was published when?

A 2001.

Q In 2001, I believe you left the Cleveland Clinic to go to Magee-Womens Hospital at the University of Pittsburgh?

A Yes.

Q Why did you do that?

A I --

THE COURT: What do you do now?

THE WITNESS: I serve as a consultant for Mr. Slater.

THE COURT: Do you do anything else besides that now?

THE WITNESS: Yes.

THE COURT: What else?

THE WITNESS: As we mentioned, I serve as a peer reviewer for medical journals. I serve as a mentor for medical students at my alma mater, the University of Maryland. And I also write. I just completed a commentary, for example, for the *British Journal of*

Obstetrics and Gynecology in relation to an article that I had reviewed.

THE COURT: Okay, what did you do before you did these things? Did you have a different position?

THE WITNESS: Yes.

THE COURT: What was that?

THE WITNESS: The timeframe, if I can ask, Your Honor?

THE COURT: How long have you been a consultant for Mr. Slater?

THE WITNESS: Since 2010.

THE COURT: And how long have you been writing peer-reviewed journal articles?

THE WITNESS: Since 1988.

THE COURT: And how long have you been reviewing, a peer reviewer for journal articles?

THE WITNESS: Since 1992.

THE COURT: What did you do before you started working for Mr. Slater?

THE WITNESS: After I retired from my surgical practice in 2004, and my clinical practice in 2006 -- we can talk about why that

had to happen -- I continued working for the NIH until the end of 2007, and then primarily for health reasons, I stepped down from that position, when I was also confident that it would be able to carry on under new leadership, and it has. And then I continued medical editing and writing until I became a consultant with Mr. Slater.

THE COURT: This says 1999 to 2007, Medical Officer, Program Director for Research on Female Pelvic Floor Disorders. What would that be?

THE WITNESS: Yes, so that's my work with the NIH that I was describing. From 1999, after I completed my masters degree, to 2007, when I retired from that position.

THE COURT: Okay, and you retired in 2007; is that right?

THE WITNESS: From the NIH, yes.

THE COURT: Any further questions on qualifications?

MR. SLATER: Just a few, Your Honor.

BY MR. SLATER:

Q In 2001 you went to Magee-Womens Hospital at

the University of Pittsburgh, why did you do that?

A The primary reason for doing that was to start a new fellowship program there, which they hadn't had in the past, and I did develop the program there and served as program director until I left the University of Pittsburgh.

At this point the fellowship in what was now called female pelvic medicine and reconstructive surgery, which is just a long name for urogynecology had become a three-year fellowship. Remember I went through a one-year fellowship when no other types were available, but by that point 3-year fellowships were available.

Q Did you continue to teach at University of Pittsburgh Medical School?

A Yes.

Q Were you a licensed physician and in what states?

A Yes. I was licensed in Connecticut, Ohio, and Pennsylvania.

Q And you stopped practicing medicine about 2006. Just tell the jury briefly why that was?

A Yes. So unfortunately, I sustained an injury in 1996 and worked through that for quite awhile,

but eventually I found that the demands were too much for me and so, as I mentioned, I retired from my surgical practice first and then continued with my clinical practice. I have a pain syndrome and I am standing here because it's more comfortable for me to stand than it is to sit for prolonged periods.

Q Did you maintain your medical license after it lapsed or did you let it go?

A No.

THE COURT: After it lapsed she let it go. Any further questions?

BY MR. SLATER:

Q In looking at your CV, there were a few things in the Professional Service section, I just want to ask you what this means: That you were a member of the Board of Directors of the American Urogynecology Society 1988 to 2001 and 2003 to 2006. What does that involve?

A The American Urogynecology Society is a professional organization where doctors and scientists with similar interests meet. The Board of Directors, of which I was a member, serves to provide direction to the organization in terms of what they would like to focus on in the future.

Q Were you in examiner for the American Board of Obstetrics and Gynecology?

A Yes.

Q What does that mean?

A In order for doctors to become Board certified they have to go through an oral examination. So I was one of the doctors who served as an examiner, testing the younger doctors as they wanted to become Board certified.

Q Were you on the editorial board of *Obstetrics and Gynecology?*

A Yes.

Q What does it mean to be on the editorial board of a medical journal?

A I was more active as a peer reviewer for that journal. So instead of receiving a manuscript maybe every month or every other month, I was assigned five to ten per month where I would review them, and we would meet annually as a group as the editorial board, similar to the role of board of directors, to see what the future of the journal should be and how we could get it to that point.

Q In your surgical practice, did you utilize mesh for certain procedures?

A Yes.

Q Did you use sutures for certain procedures?

A Yes.

Q Did you treat prolapse on a regular basis surgically?

A Yes.

Q Are you familiar with the various procedures that are at issue in this case?

A Yes.

MR. SLATER: Your Honor, at this time we would offer Dr. Weber as an expert in the field of urogynecology?

THE COURT: Are there any questions on qualifications?

MS. ROBINSON: No, Your Honor.

THE COURT: Okay, ladies and gentlemen, the witness is qualified to provide expert opinion testimony in her fields of expertise. Proceed.

\- - -

DIRECT EXAMINATION

\- - -

BY MR. SLATER:

Q Doctor, do you understand that any opinion you

offer in this case must be to a reasonable degree of medical certainty?

A Yes.

THE COURT: Before we go further, are you offering into evidence her CV?

MR. SLATER: Not at this time, Your Honor.

THE COURT: Fine. Fair enough.

Q So, Doctor, if you offer us an opinion we are going to understand it's to reasonable degree of medical certainty unless you tell us otherwise. Do you understand that?

A Yes.

Q Now, for the work you have done in this case, the case we are in court for, have you been paid for the time you've spent?

A Yes.

Q And have you issued invoices for and/or plan to issue further invoices for work you have done in more recent time?

A Yes.

Q And are you going to be paid for the time you spend in this courtroom?

A Yes.

Q And what do you charge to come to court like this for a jury?

A Courtroom testimony, I have a charge of $1,000 per hour.

Q Now let's put up, we have a PowerPoint of materials you have reviewed. Let's put that up.

Doctor, this List of Materials Reviewed, what is that, simple terms?

A So this is a list of the kinds of materials I have reviewed in the course of my work with Mr. Slater.

Q Did you estimate the number of pages of documents from Ethicon and medical literature and clinical study, Doctor, is there any way to estimate the volume of documents you have looked at?

A We have made an estimate of over one million pages of documents.

Q And your review of these materials, are these materials you intend to rely on in offering your opinions here today?

A Yes.

Q And I will just read it for the record: Medical literature, clinical and preclinical studies, including underlying data, Ethicon/Johnson

& Johnson internal documents?

THE COURT: Well, we can read it. Is that what you relied on?

THE WITNESS: Yes.

THE COURT: Okay, next question. You can keep it up as long as you would like.

Q I am ready to go to the next line, Treatment Options.

Doctor, we have a slide up here, Treatment Options. Can you tell us what this represents?

A So there are many options for treating women with prolapse, which depends entirely on their symptoms.

Q And just going through them very quickly, what is each?

A So the first represents observation, which is watchful waiting. This is not a dangerous condition, not something that changes quickly. If a woman is not symptomatic or only minimally symptomatic, this is a perfectly reasonable option.

Q Pessary, we have heard about so we are going to skip that.

Suture repair, just very briefly, what

are we talking about?

A Suture repair, colporrhaphy is the medical term for suture repair, either in the front wall or the back wall of the vagina, where sutures are used to bring the tissue together and strengthen the wall of the vagina.

Q And abdominal sacrocolpopexy, we heard what that is, just one sentence or so to show you know what it is?

A A procedure that lifts the top of the vagina and using another type of material attaches it to the back of the tailbone in order to provide support.

Q The suture repairs and the abdominal sacrocolpopexy, did you perform those routinely in your practice?

A Yes.

Q Next, biologic or synthetic graft augmented repair. What are we talking about there?

A So using another type of material, biologic may be something like cadaveric fascia or other products that are developed from animals where they are in a layer that can be used to help support the organs. And synthetic in the same way except,

obviously, that's something that's manmade.

Q Did you perform procedures with those techniques?

A Rarely.

Q Mesh kit, something like the Prolift. Now I understand the Prolift came on the market after you stopped operating on patients, correct?

A Yes.

Q Are you familiar with the Prolift and the mesh material?

A Yes.

Q Are you familiar with the procedure, the instruments, how it's performed?

A Yes.

Q Have you reviewed surgical videos, their surgical documents, their internal documents on how it's to be done?

A Yes.

Q Doctor, with regard, and I am only going ask this question one time just to situate, do you have an opinion as to whether suture repair and/or abdominal sacrocolpopexy would have been a safer alternative than the Prolift for her treatment?

A Yes.

Q And very simply, why is that?
A Because either of those types of procedures would have been successful in resolving her symptoms without introducing the set of complications which she has developed.
Q The synthetic graft augmented repair -- I am not going to go into that. Let's go to the slide now P1660.
Doctor, this PowerPoint, are you familiar with this?
A Yes.
Q And LIGHTning, what is LIGHTning.
A I am sorry?
Q Right on the front it says LIGHTning. What is project LIGHTning?
A It was Ethicon's code word for the development of a new product after Prolift.
Q What was that ultimately called?
A That was Prolift Plus M.
Q And this PowerPoint is by Peter Meier, he was a scientist at Ethicon.
A Yes.
Q And what is the date on the top right?
A September 6, 2006.

Q What I would like to turn you to now is page 14, and the pages are numbered.
Is this PowerPoint something you relied on in forming your opinions in this case?
A Yes.
Q And we have here on the screen, it says a, Human Cadaver Wet Lab was performed with Dr. Kurt Lobodasch. What does that mean, a cadaver lab?
A A cadaver lab is where cadavers are set up in a laboratory where they are positioned in such a way they can be used for testing whatever it is that you want to be testing.
Q And here it says, "There was a successful cadaver lab with Dr. Lobodasch." Do you see that?
A Yes.
Q I am going to ask you a couple of things and ask if they are significant. The first two, "Preferred Ultrapro over Gynemesh PS." Is that significant to you?
A Yes.
Q Very simply, what is Ultrapro?
A Ultrapro is an Ethicon mesh that is partially absorbable and partially permanent polypropylene.
Q And the Gynemesh PS is what?

A Is the permanent polypropylene mesh in the Prolift.
Q He says, "Better handling of Ultrapro with Prolift instruments," is that significant to you?
A Yes.
Q Why is that?
A This doctor is expressing that the handling, just the hand feel and how he is able to work with the Ultrapro mesh with instruments is better than what he was experiencing with the Gynemesh.
Q And a little further down it says, "Feels very soft in place." Is that significant?
A Yes.
Q Why is that?
A If he says the Ultrapro is very soft, then by comparison the Gynemesh must be less soft.
Q Why is that significant in a pelvic floor treatment?
A Ideally, that would correspond to how the mesh behaves in the woman.
Q It says, "No crumpling of arms compared to Gynemesh PS." And those arrows, they are on the document, right?
A Yes.

Q Is that significant to you?
A Yes.
Q Why is that significant?
A As you can see, the crumpling of the arms with the Gynemesh PS, this is exactly what happens in person. And I know you have seen the videos where you have see the roping of the mesh arms and the complications that occur as a result of that. The Ultrapro does not have that appearance and ideally, it would not have that behavior as the Gynemesh PS showed.
Q What if any significance is there to the arm crumpling or roping in the body of an actual patient, what does that do?
A So when the mesh is crumpled, that increases the amount of mesh in that area. And the more the mesh is bunched up together, that increases the inflammation, the foreign body reaction, the pores are scrunched down so that the tissue can't grow in there as it's intended to do. Instead, it forms this fibrotic ridging, scar plating that turns the mesh into this rock-hard, caked piece of tissue and mesh instead of something where the tissue has been able to lay flat along with the mesh and not cause

so many complications.

Q And that issue that you just described, the crumpling, the bunching of mesh, is that something that Ethicon was knowledgeable about based on your review of the materials?

A Yes.

Q And even at this time, as of September 2006?

A Yes.

Q And then it stays, "Near to my expectation of replacing pelvic floor tissue." Is that significant?

A Yes.

Q Why is that?

A The idea of putting mesh in the vagina was to reproduce the normal tissue, and the problem is that a hernia mesh that Ethicon took and transposed into Gynemesh PS, the exact same mesh, was not behaving in the vagina in a way that was anything like normal vaginal tissue. And the hope was within Ethicon that the Ultrapro would do a better job of acting like the normal vaginal tissue.

Q Let's go down to page 22. This is talking about in vitro testing. That would be lab testing of the Ultrapro?

A Yes.

Q Is that something Ethicon relied upon in the business to evaluate meshes?

A Yes.

Q And the third bullet point says, "Area weight (lightness) that Ultrapro is lighter than Gynemesh, Vypro and most competitors." Is the lightness of the mesh significant?

A It can be, yes.

Q Why is that?

A So by lightness they are referring to basically the amount of mesh, and theoretically, it would be best for the woman to have less mesh remaining in her body.

Q Why is that?

A Because the more mesh there is, it becomes a cascade of the inflammatory reaction or body reaction, the scar plating and bridging fibrosis, that leads to all kinds of other complications, mesh erosion, vaginal anatomic distortion, and, you know, the woman experiences dyspareunia and pelvic pain, and just turns into a vicious cycle where the more mesh there is, it's like feeding wood to a fire.

Q It says, Pore Size. "Ultrapro has larger pore

size than Gynemesh PS, 3 to 5 millimeters compared to 0.3 to 2.4 millimeters." Is that significant?

A Yes.

Q And when they are talking about these pore sizes they are talking about the mesh before it's been put in the body, right?

A Yes.

Q Why is the pore size significant and what's the difference between before it goes into the body and when it goes into the body, what's the issue there?

A The pore size is significant because it's been established that the pores have to remain in a diameter of one millimeter in all directions to avoid this phenomenon of the fibrotic bridging. When the pores are smaller than that, it's easier for the body's tissues, the collagen and whatnot, to grow across the mesh and pull it together and cause the mesh shrinkage and then all the things that we have already been talking about.

Q Do you have an opinion as to whether the Prolift+M with the Ultrapro mesh was a safer alternative to the Prolift?

A Yes.

Q What is that opinion?

A It was safer.

Q Why is that?

A Because it was lighter and left less mesh in a woman after the absorbable part went away, and because, at least in theory and before it got placed in a woman, the pore sizes were larger and would able to avoid this phenomenon of the fibrotic bridging, et cetera, et cetera.

Q Doctor, I have given you a large document that I promise we are only going to go through a little bit of. This is Exhibit P625, and this is -- first of all, there is an E-mail, November 1st, 2010, from Peter Meier, enclosing the updated report on erosion of meshes. Correct?

A Yes.

Q And this is the same Peter Meier who authored that PowerPoint we just saw with the jury?

A Yes.

Q Let's turn to the actual first page of the report and just show that to the jury so they can see the front page. And it shows, September 13, 2010, Clinical Evaluation Report, Mesh Erosions, by Peter Meier, Principal Scientist at Johnson &

Johnson Medical. Correct?

A Yes.

Q What I would like to now is first ask you, Charlotte Owens who is the Medical Director, did she testify as to whether or not she was aware of those complications and issues we are going to discuss now?

A Yes.

Q Did she say she knew about those before the Prolift was launched?

A Yes.

Q Let's go to Section 2.2, which is on page seven. If we go down to the second paragraph, the second sentence --

MR. SLATER: If it's okay, Your Honor, I would like to read it and ask the expert if she has an opinion about it.

THE COURT: Let's try it fresh and then we will see how it turns out.

Q The second sentence, "Mesh material-related adverse events included infections, erosions extrusions, mesh shrinkage, vaginal granulation tissue, sinus formation, abscesses, fistulas, osteomyelitis."

I am going to stop there. Is that information significant to you?

A Yes.

Q And I neglected to ask, is this entire report something you relied on in forming your opinions?

A Yes.

Q Are you familiar with this document?

A Yes.

Q Why is that sentence significant to you?

A That is significant because it lists just some of the extremely serious complications that can occur after the implantation of this permanent mesh that are directly related to the mesh characteristics itself.

Q Now let's go to Page 8, Section 3 titled, Etiology of Mesh Erosions, the first paragraph. It says "Erosion means superficial --

MS. ROBINSON: Objection.

THE COURT: I will see you at sidebar.

(The following transpired at sidebar:)

THE COURT: What's your objection?

MS. ROBINSON: Your Honor, I am objecting to him just throwing up slides and reading them to the witness and asking him if

they are significant to her. It's not a proper way to ask an expert questions.

THE COURT: (Direct to the Jury:) Ladies and gentlemen of the jury, we are going to break at this time while I deal with this objection. I will ask you to return tomorrow at 9:30. Between now and when you return, keep an open mind and don't discuss the case with anyone. Is it too late to remind you not to discuss the case with anyone? Please don't discuss the case with anyone.

Bring the jury out.

(The jury is excused from the courtroom at 4:33 p.m.)

THE COURT: I will see counsel in Chambers on the record.

(The following transpired in the robing room with counsel present:)

THE COURT: Okay, what's the problem?

MS. ROBINSON: Your Honor, I have been fairly patient with counsel just putting documents up in front of the witness, reading them to her and asking then if that particular part is significant to her. I think the

appropriate way to examine her is to show her the document, say what about the document did you use to rely upon to form your opinions.

MR. SLATER: Your Honor, I think that there is nothing wrong with identifying a portion of a 122-page document, the portions that we believe are significant, identifying them for the jury and then, whether I read them or the expert reads them, letting the jury know what is at issue and then letting the expert provide the opinion, which is the significant part of it, so that there is an opinion linked to a foundation, rather than having the expert just speak. She may not talk about the parts I want to address and we have to go round and round.

THE COURT: In other words, you have to lead her.

MR. SLATER: Sort of lead her.

THE COURT: The objection is sustained.

Is there anything else we can accomplish today?

MS. ROBINSON: Your Honor, I do want to raise once again the witness' intent to go

through the Lucente database. There is a number of things wrong with it, I think in terms of, one, it's not relevant and it's highly prejudicial. This database isn't a database that Ethicon owned, it's not information that Ethicon was provided. It is highly unreliable because --

THE COURT: Wait a minute, it's highly unreliable?

MS. ROBINSON: Yes.

THE COURT: Can you demonstrate that?

MS. ROBINSON: The two investigators --

THE COURT: Can you demonstrate that it's highly unreliable? Is that just lawyer talk?

MS. ROBINSON: It's maybe hyperbole but --

THE COURT: Well, then let's stick to what you can demonstrate. All right? Your hyperbole is stricken from the record as not something that will ever be supported by the evidence. So let's stick to what the evidence will show.

MS. ROBINSON: The Lucente database,

Your Honor, is a retrospective study that Vincent Lucente started along with his partner Dr. Murphy, and they obtained a grant, a $12,500 grant from Ethicon. The data was data that they already had in their practice in patients that they had operated on. As a part of this grant they were to put together a retrospective study of their patients and eventually publish it. They never published it and didn't get the last payment from Ethicon for that.

The data was owned by Lucente and his facility. Ethicon had the right to inspect it at points in time if they desired. The data is -- the witnesses will testify and have probably testified that there are a number of different patients. So the data that was provided --

THE COURT: Can we get back to what is objectionable about it?

MS. ROBINSON: It's completely unreliable.

THE COURT: Can you demonstrate that?

MS. ROBINSON: Walking through a number

of different hoops.

THE COURT: However many days you need, can you demonstrate in cross-examination of anybody who relies on this database that they don't know what they are talking about or they are relying on something that's unreliable?

MS. ROBINSON: It was never complete, and I think the burden --

THE COURT: Does that mean the answer is yes or no?

MS. ROBINSON: The answer is yes.

THE COURT: Okay. Then you will demonstrate that this person is nothing more than a paid professional witness, relying on things that are demonstrably unreliable. The objection is once again overruled.

Is there anything else we can accomplish today?

MR. SLATER: Just to avoid anything tomorrow, based on Your Honor's ruling, my intention would be to at least draw Dr. Weber's attention to specific paragraphs.

THE COURT: Okay. Would you object to that?

MS. ROBINSON: I think it depends on how it proceeds.

THE COURT: How it proceeds? It's going to proceed exactly the way it proceeded today. Are you going to object to that?

MS. ROBINSON: If it proceeds exactly the way it proceeded today, yes, Your Honor.

THE COURT: That will be sustained, too.

MR. SLATER: If I say, I just want you to look at this paragraph, ask her what it is talking about, and let her testify how it matters to her?

THE COURT: What opinions is she going to offer?

MR. SLATER: She is going to offer opinions about the mesh, about the involvement --

THE COURT: Why don't you start with the opinions, but I am not going to tell you how to do whatever you want to do. But to me, so far, this is just totally floating in the ether.

Anything further?

MS. ROBINSON: No, Your Honor, thank you.

THE COURT: See you tomorrow morning at 9:30.

- - -

(Hearing is adjourned at 4:35 p.m.)

- - -

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR
OFFICIAL COURT REPORTER
COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.

Case 2:12-md-02327 Document 2182-2 Filed 05/09/16 Page 23 of 110 PageID #: 62859

Case 2:12-md-02327 Document 2182-2 Filed 05/09/16 Page 24 of 110 PageID #: 62840

In The Matter Of:

Hammons v.

Ethicon, et al.

(Jury Trial-Morning)

Vol. VI

December 8, 2015

John J. Kurz, RMR, CRR, Official Court Reporter

City of Philadelphia

First Judicial District Of Pennsylvania

100 South Broad Street, 2nd Floor

Philadelphia, PA 19110

Original File 08DECEMBER-2015-HAMMONS-AM-FINISHED.txt

Min-U-Script® with Word Index

(Jury Trial-Morning) Vol. VI - December 8, 2015
Hammons v. Ethicon, et al.

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION

PATRICIA HAMMONS, Plaintiff : MAY TERM, 2013

v.

ETHICON, INC., et al., Defendants : NO. 3913

TUESDAY, DECEMBER 8, 2015

COURTROOM 246
CITY HALL
PHILADELPHIA, PENNSYLVANIA

B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J., and a Jury

JURY TRIAL - VOLUME VI

MORNING SESSION

REPORTED BY:
JOHN J. KURZ, RMR, CRR
REGISTERED MERIT REPORTER
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

A P P E A R A N C E S:

KLINE & SPECTER, A Professional Corporation
BY: SHANIN SPECTER, ESQUIRE
BY: KILA B. BALDWIN, J.D., ESQUIRE
1525 Locust Street
The Nineteenth Floor
Philadelphia, Pennsylvania 19102
T: 215-772-1000 F: 215-735-0937
E-mail: shanin.specter@klinespecter.com
kila.baldwin@klinespecter.com
Counsel for Plaintiff Hammons

MAZIE, SLATER, KATZ & FREEMAN
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
T: 973-228-0454 F: 973-228-0303
E-mail: aslater@mskf.net
Counsel for Plaintiff Hammons

DRINKER BIDDLE & REATH, LLP
BY: MOLLY E. FLYNN, ESQUIRE
One Logan Square, Suite 2000
Philadelphia, Pennsylvania 19103-6996
T: 215-988-2836 F: 215-988-2757
E-mail: molly.flynn@dbr.com
Counsel for Defendants Ethicon and Johnson & Johnson

TUCKER ELLIS, LLP
BY: MATTHEW P. MORIARTY, ESQUIRE
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113-7213
T: 216-696-2276 F: 216-592-5009
E-mail: matthew.moriarty@tuckerellis.com
Counsel for Defendants Ethicon and Johnson & Johnson

A P P E A R A N C E S: (Continued)

GOLDMAN, ISMAIL, TOMASELLI, BRENNAN & BAUM, LLP
BY: TAREK ISMAIL, ESQUIRE
(admitted pro hac vice)
564 West Randolph Street, Suite 400
Chicago, Illinois 60661
T: 312-681-6000 F: 312-881-5190
E-mail: tismail@goldmanismail.com
Counsel for Defendants Ethicon and Johnson & Johnson

THOMAS COMBS & SPANN, PLLC
BY: SUSAN M. ROBINSON, ESQUIRE
(admitted pro hac vice)
300 Summers Street, Suite 1380
Charlestown, WV 25338
T: 304-414-1800 F: 304-414-1801
Counsel for Defendants Ethicon and Johnson & Johnson

Also Present:

Charles Tasco, Court Crier

- I N D E X -

- I N D E X - (Continued)

E X H I B I T S

P R O C E E D I N G S

(Time: 9:45 a.m.; Morning Session.)

- - -

(The following transpired in open court outside the presence of the jury:)

- - -

THE COURT: Is there anything we can accomplish now?

MR. ISMAIL: One issue we'd like to address, Your Honor.

THE COURT: Yes, sir.

MR. ISMAIL: This relates to the testimony of Dr. Weber. In the proffer that counsel made to the Court, there was a specific exchange as to whether or not Dr. Weber would address Mrs. Hammons.

THE COURT: Yes.

MR. ISMAIL: And there was a representation that there was no such testimony expected from Dr. Weber.

THE COURT: Yes.

MR. ISMAIL: Upon reviewing the transcript last night, there was a question -- two questions and answers which used the pronoun "her" rather than Ms. Hammons. But in reviewing

the transcript in context --

THE COURT: What page?

MR. ISMAIL: So the question and answer was -- the first one is at Page 240, Line 20.

I have a copy.

THE COURT: I got it.

MR. ISMAIL: Very good.

THE COURT: Yeah. Any other?

MR. ISMAIL: And then the follow-up question onto Page 241, "And very simply, why is that?"

And then the witness volunteers her symptoms in the answer.

THE COURT: Yeah. Yeah.

And she also put up -- or counsel put up that she confirmed a list of everything that she had reviewed. Were there any medical records of Ms. Hammons --

MR. SLATER: Yes.

THE COURT: -- on that list?

There were, okay.

You did not mention that in your offer of proof, correct?

MR. SLATER: I'm going to try to find

the exact words, Your Honor.

THE COURT: Fine. Good.

MR. SLATER: When I talked about it --

THE COURT: Wait. If you're going to try to find the exact words, then we'll wait.

MR. ISMAIL: May I?

THE COURT: May you what?

MR. ISMAIL: Show you his exact words.

THE COURT: Yeah. That would be great. Where is his exact words?

MR. ISMAIL: Page 209.

MR. SLATER: Is this the proffer?

MR. ISMAIL: This is the proffer.

THE COURT: 209.

MR. ISMAIL: And at Line 18, Your Honor asked the question, and the response is given at Line 22.

THE COURT: "I do not intend to elicit any opinions specific to the plaintiff."

Was that another mistake, Mr. Slater?

MR. SLATER: Your Honor, the two things that happened yesterday were, number one, the materials reviewed, as I learned with

Dr. Elliott, the full amount of things she reviewed should be there so that it's understood what she saw. I didn't want her to then be cross-examined, hey, you didn't tell us you saw these things.

The issue with the alternative procedures is simply this: I couldn't ask the question, I didn't think, logically without placing it in the context of the patient; that these were alternatives available that would be reasonable for her. That's it.

THE COURT: What's it?

MR. SLATER: That's all I did. I didn't think there was any other way to place it -- to put it in without an appropriate context.

THE COURT: So this was not a second mistake. This was an intentional asking about her after having said in your offer of proof that you don't intend to elicit anything specific to her; is that what you're telling me?

MR. SLATER: I -- I -- I don't see it as a intentional violation of anything. I wasn't trying to violate anything. I made the proffer as best I could, Your Honor.

THE COURT: No. I don't know about violate. But it was inconsistent, intentionally inconsistent with what you had said at the proffer, right?

MR. SLATER: I didn't know how else to make it relevant, Your Honor.

THE COURT: "I didn't know how else," which means that I've thought about it and I decided that this is how I should do it even though in the proffer I had said the exact opposite; is that what you mean?

MR. SLATER: I don't believe that I mean that I intentionally did anything, Your Honor.

THE COURT: Okay. So then how could it happen that on a proffer you specifically say I don't intend and then 60 pages later you ask the exact question?

MR. SLATER: When I talked about --

THE COURT: It's not a mistake and it's not intentional. Tell me what it is, then.

MR. SLATER: What I intended when I talked about Ms. Hammons was that we weren't going to ask causation questions or about what happened to her due to the mesh. That's what I

was talking about. That's what I intended to convey; that we weren't going to go through her medical course, say this was caused by this, that was caused by that. I wasn't going to get into it and we're not going to. That was what I intended to convey, Your Honor.

And if the issue of the proffer was whether she was qualified, she certainly is qualified to have said these were safe alternatives for this patient.

THE COURT: So, "I do not intend to elicit any opinions specific to plaintiff." Any means what?

What does the word "any" mean in that context?

MR. SLATER: I understand what it means, Your Honor.

THE COURT: What does it mean? Because maybe we're using a common word to mean two different things.

MR. SLATER: My intention was talking about --

THE COURT: No. What does the word "any" mean in that sentence?

MR. SLATER: I assume it means any.

I don't have a definition.

THE COURT: You can't define -- no definition of the word "any."

MR. SLATER: I think "any" has a common, understood term. I'm not disputing --

THE COURT: And what is your commonly understood term?

MR. SLATER: Any means none.

THE COURT: "None."

MR. SLATER: But I was intending to convey causation opinions, which was I thought what they were concerned about from the conversation.

I was rushing through this. I went as quickly as I could, but that's what I intended to convey. And, again, the proffer was for purposes of them to object to her testimony. There was no legitimate objection to her qualifications.

THE COURT: No. The proffer -- I don't know what you thought the proffer was for. I don't read minds, but the proffer was so that you could tell opposing counsel what of the 500-plus pages of her report they had to expect in testimony. Because it would be improper, in

my opinion, to force counsel to expect anything in an overly inclusive, obviously huge amount of paper.

Yes. So what flows from this, Counsel?

MR. ISMAIL: Your Honor, what flows from this, we think the question and answer should be stricken from the record. The jury should be instructed that Dr. Weber is not offering any opinions and her testimony is not as to Mrs. Hammons.

And I'll point out, Your Honor, that the second question, Dr. Weber volunteered the very causation opinion --

THE COURT: Remind me what page it is. I didn't mark it.

MR. ISMAIL: 241, Line 3 is the beginning of her answer.

THE COURT: That's not a causation opinion.

MR. ISMAIL: "Without introducing the set of complications she has developed."

THE COURT: I don't think it's a causation opinion.

So what do you want me to do? You

want me to read it to the jury and tell them to disregard it?

MR. ISMAIL: I would like -- no, in answer to your question, Your Honor.

We would like Your Honor to strike Pages 240, Line 20, through 241, Line 6, and that the jury should be instructed that Dr. Weber does not -- is not offering any opinions about Mrs. Hammons.

THE COURT: So can you tell me why you didn't object when that happened.

MR. ISMAIL: Your Honor, the question -- well, given the proffer, we weren't expecting testimony about Mrs. Hammons. The question didn't have Mrs. Hammons in the name -- in the form of the question. Actually until we went back and looked and saw the pronoun "she" in the question and the answer did we realize what had been elicited from the witness.

THE COURT: Okay. Mr. Slater, do you wish to address that request?

MR. SLATER: Your Honor, we object to that request.

The ultimate reason -- and I understand that they wanted notice --

THE COURT: Wait. As I believe, it was the Court that said what's your proffer.

MR. SLATER: Yes, Your Honor.

THE COURT: And you didn't want to tell them, give away your full direct examination. And I think I said you don't have to, but it makes their objection easy.

So do you want to address the remedy that defense is asking for.

MR. SLATER: Yes, Your Honor. I think that that remedy should not be imposed. Dr. Weber's testimony is appropriate. It is -- she's well-qualified to provide that opinion. There was no -- again, there was no surprise to them. They know she held that opinion. It's very narrow on one narrow issue. They did not object. I could have cured it at that point and just said, okay, let's talk in general if they objected to the mention of "her," and that's it. I used one pronoun. I understand. I do not dispute what Your Honor is saying. I'm telling you what I sincerely believed when I told you what I was going to do. There is no cause to strike any testimony. The opinion's appropriate. And they have no reasonable

objection to her qualification or that they were not on notice that she had that opinion since she's always held that opinion in this case.

THE COURT: Anything further? Is there anything further?

Is there anything further?

MR. ISMAIL: No, Your Honor.

THE COURT: Okay. The testimony at Page 240, Line 20, through 241, Line 6 is stricken, and the Court will instruct the jury about the limits of Ms. Hammons -- of Ms. Weber's testimony; namely, that there will be no specific opinions about Ms. Hammons offered.

Is there anything further that we can accomplish at this time?

MR. SLATER: No.

MR. ISMAIL: No, Your Honor.

THE COURT: Okay. We'll wait for the juror.

(Pause in the proceedings.)

THE COURT: Charles is bringing in the jury.

MR. SLATER: Judge, should I have Dr. Weber go up first or wait till the jury is

seated?
THE COURT: Hold on. No. You better wait.
COURT CRIER: Please remain seated until the jury has reached the jury box.
- - -
(Whereupon the jury entered the courtroom at 10:01 a.m.)
- - -
(The following transpired in open court in the presence of the jury:)
- - -
THE COURT: Good morning, ladies and gentlemen.
JURY PANEL: Good morning.
(Witness resumed the witness stand.)
COURT CRIER: Raise your right hand. Do you solemnly swear or if you affirm, do you affirm that you will answer every question truthfully?
THE WITNESS: Yes.
COURT CRIER: State your name for the record, please.
THE WITNESS: Anne Margaret Weber.
COURT CRIER: Spell your last name.

THE WITNESS: W-E-B-E-R.
COURT CRIER: Thank you. Please keep your voice up for the jury, please.
THE WITNESS: Thank you.
THE COURT: Ladies and gentlemen of the jury, yesterday you may have heard or understood some of the testimony to apply to a specific opinion concerning Ms. Hammons. This expert, Ms. Weber, has not been called to offer any opinions specifically about Ms. Hammons. So if you understood any testimony to refer specifically to Ms. Hammons, you are to disregard that testimony. It's stricken from the record.
Are we ready to go?
MR. SLATER: We are, Judge.
THE COURT: Proceed.
MR. SLATER: Thank you.
- - -
... ANNE M. WEBER, M.D., after having been first duly sworn, was examined and testified as follows:
- - -
DIRECT EXAMINATION
- - -

BY MR. SLATER:
Q. Good morning, Dr. Weber.
A. Good morning.
Q. Doctor, in order to speed things along, I've stacked up a series of exhibits in front of you. We'll go through them in order. I'm not going to have to walk up and hand them to you, so I'll just identify them as we go, okay?
A. Yes.
Q. Okay. What I'd like to start out with is the exhibit on the top of the pile, it's P-1666.
And is this a document you're familiar with?
A. Yes.
Q. Please tell the jury what that document is.
A. This is an abstract that was presented at a scientific meeting representing results from one of the Ethicon-sponsored studies about the Gynemesh PS mesh.
Q. What was the name of that study?
A. Gynemesh PS Mesh.
Q. Okay. And what was it that the doctors were doing in that study?
A. They were using the Gynemesh PS mesh in different prolapse operations, abdominally and

vaginally, in the treatment of women with prolapse.
Q. And they were evaluating how the mesh reacted in the body?
A. Yes.
Q. Just one thing, you don't have to lean down to the mic.
A. Okay.
Q. I don't want to make you uncomfortable.
Okay, Doctor. Now, who are the investigators? Who were listed as the investigators for the study or the ones that authored this abstract?
A. The authors of this abstract are Dr. Lucente, Dr. Hale, Dr. Miller -- those are urogynecologists who are paid consultants of Ethicon -- and Dr. Madigan who is an Ethicon employee.
Q. Now, did you have an opportunity to review data with regard to this study?
A. Yes, I did.
Q. And what did you do in order to evaluate what was found by the study? Tell the jury what you did.
A. I reviewed the Case Report Forms, which is a term that's used in research to describe what we call the raw data. So before it gets collected all together and the analysis begins, where -- whoever

is recording the data is actually putting down the information about that patient on paper.

Q. And tell us a little more about a Case Report Form. What's the purpose and how are they constructed? And you can talk about the ones in this study specifically.

A. Yes.

So the Case Report Forms include the information that's intended to be collected in the course of the study. The patient is assigned a number so that it doesn't -- her name isn't on the paper so this is, for the purposes of the patient, is important for confidentiality. And then there's a set of documents that are the beginning and then different points in time as she goes through follow-up. And this is to record what's been specified in the protocol as to the important points to consider.

And something that's important to remember is that if it's not in the protocol and it's not on the Case Report Form, if it's not specifically asked for, you can easily realize it's not going to be captured. That piece of information won't get captured.

Q. Was there any type of medical issue that was

not listed on the Case Report Forms that was significant to you?

A. Yes.

Q. Tell the jury what wasn't asked for on those forms.

A. The Case Report Forms didn't have any recording -- any spot to record specifically the recurrence of mesh contraction or retraction, which is a very important complication that occurs with Gynemesh PS mesh.

Q. Okay. Now, this abstract, this was presented someplace to other doctors?

A. Yes.

Q. And there's data on it and results listed, right?

A. Yes.

Q. Okay. Let's put up the PowerPoint slide of the Gynemesh PS study, please.

(Technician complied.)

(Document displayed.)

BY MR. SLATER:

Q. Okay. Doctor, please walk the jury through what this slide that was prepared -- what that shows; what that tells the jury.

A. Yes.

So the study abstract reports certain results, including the mesh exposure which has also been termed mesh erosion, the prolapse recurrence rate, meaning does the prolapse come back. And Ethicon, in the context of this abstract, reported certain rates. As you can see, 9.4 percent of women who experienced a mesh exposure by one year and 24 percent of women who experienced a prolapse recurrence by one year.

Q. How many patients were studied?

A. All together, 169 patients were entered into the study. A smaller number of those women reached one year of follow-up, and that's represented in the 129 patients there.

Q. Now, so you have the Ethicon rate, those are the rates that are in this abstract that was reported?

A. Yes.

Q. What is the column "actual corrected"? What does that mean?

A. So that represents what I calculated based on my independent review of the Case Report Forms themselves.

Q. Now, the way that you reviewed these Case Report Forms -- first of all, what kind of a volume

of paper are we talking about?

A. Well, for each patient, 169 to start, 129 to follow, there would be about 30 pages for each patient.

Q. And you reviewed that your own -- on your own, yourself?

A. Yes, I did.

Q. When you reviewed this data, did you review this data differently than you would have if you were involved in a clinical study that you were seeking to present at a national meeting or to ultimately publish -- the types of things you've done in your career?

A. No, it was exactly the same.

Q. And tell the jury your findings when you reviewed the data on your own.

A. So what I found in terms of mesh exposure was that it had actually occurred to 24 women, which represents 15.4 percent. And for the prolapse recurrence, that it had happened to 47 women with a slightly larger denominator, as you can see there, 139, which represents almost 34 percent. So that's quite a bit deal higher than what had been reported in the abstract.

Q. Now, you have something about the data

collection forms. You touched on this. Just please explain what that means, that note right there.

A. Yes.

So just like we were just talking about a minute ago, if it's not on the form, it's not going to be collected. So on these data collection forms, there were no specific areas to record mesh contraction and retraction that we talked about, dyspareunia, which is pain with sex, pelvic pain or vaginal pain. And then just below that you see the protocol had originally intended to record the presence of granulation tissue, which is reddish, nonhealing tissue that can happen in the vagina that is often a precursor, what happens before you actually see a mesh erosion develop. And that was in the protocol intended to be collected. But at some point in the future of the protocol it was decided that there was no need to collect that information.

Q. And what's your opinion on that?

A. My opinion is that that was important. It needed to be collected.

Q. Why?

A. Well, as I said, if it's a precursor to mesh erosion commonly, it's something the woman is

experiencing, symptoms are common. She can have vaginal bleeding, vaginal discharge, pain with sex. It's an important clinical event.

Q. Now, these data results, do you have an opinion as to whether or not they represent an acceptable risk-benefit profile for a procedure to treat prolapse?

A. Yes, I have an opinion.

Q. And what is your opinion?

A. My opinion is that it is absolutely unacceptable as a risk-benefit profile.

Q. Why is that?

A. Because you can see the recurrence rate is so high. When you're thinking about whether you want to do something, you think about the risks and benefits. So the benefit proposed of using mesh in the first place was it was going to repair the prolapse so much better. That's clearly not true.

In addition to not repairing the prolapse so much better, women are encumbered with this incredibly high rate of complications; and this is only one of them, the mesh erosion.

Q. Let's go to the next slide, which was the PowerPoint slide from opening.

Doctor, have you had a chance to see

this slide which was used by defense counsel in their opening statement?

A. Yes, I have.

Q. Do you have an opinion as to whether or not it's accurate to say that Gynemesh PS shows 80 to 90 percent success?

A. Yes, I have an opinion.

Q. And what's your opinion?

A. My opinion is that is not accurate.

Q. And is that for the reasons you've just explained?

A. Yes.

MR. SLATER: Okay. Take that down.

(Technician complies.)

BY MR. SLATER:

Q. Doctor, we've heard about the TVM study. Just tell the jury in general what it was, just so we have a record and a foundation. You know what it is. Briefly tell the jury, what was the TVM study? And we'll talk about that in a little bit.

A. The TVM study was a set of clinical studies performed in France with the original TVM group and also in the United States by Ethicon-paid investigators to look at the early clinical results of a prototype, not exactly the Prolift, but a

prototype of what would become the Prolift.

Q. Now, let's put up Exhibit -- hand it to counsel first before you put it up, actually.

(Exhibit P-1752 marked for identification.)

BY MR. SLATER:

Q. Dr. Weber, I'm going to ask you some questions about the next exhibit, 1752.

A. Yes.

Q. Okay. Let's put that up.

(Document displayed.)

MS. ROBINSON: Objection.

THE COURT: Don't put it up.

Yes. What's the legal basis?

MS. ROBINSON: Cumulative for the --

THE COURT: Oh, go ahead. I'm sorry. Cumulative.

MS. ROBINSON: Cumulative for the first portion of the slide. The information has been elicited by Dr. Elliott.

THE COURT: Got it. Overruled.

MR. SLATER: Thank you.

(Document displayed.)

BY MR. SLATER:

Q. Doctor, Exhibit P-1752 titled French TVM Study,

Primary Endpoint, what is this exhibit?
A. So this represents some data from the French side of the TVM study, the nine surgeon investigators who were paid by Ethicon to perform this study, like I said, on the TVM procedure, the Prolift prototype. And this represents some of their data on the recurrence rate.
Q. Now, there's two sections. First it says upper limit of 90 percent confidence interval. And we've heard about confidence intervals. You understand what's been testified to?
A. Yes.
Q. Okay. Just very simply, why is a confidence interval used?
A. A confidence interval is used in statistics and research to provide a range over what could be expected. If you did the study on a hundred different women and a hundred different women and a hundred different women, the average might be slightly different but the range would be -- they would fall within this expected range to a certain degree of confidence, and that's why we use these numbers.
The 90 percent confidence interval, so there would still be 10 percent of -- you know,

10 percent of the studies you did on hundreds of different women might fall outside this range, but at least 90 percent of them would fall within.
Q. And when that statistical analysis was done, are those the rates that Ethicon itself found on that standard?
A. Yes.
Q. You're familiar with what the primary endpoint was listed, 20 percent or greater?
A. Yes.
Q. Did this meet the primary endpoint of the study?
A. This indicated a failure of the primary endpoint.
Q. Is that both at six months and one year?
A. Yes.
Q. You have another section there, upper limit of 95 percent confidence interval, two sided. Why did you put that there?
A. That was what was in the original protocol to use this form of the statistic, and then Ethicon changed the protocol to a less strict definition. They went down from the 95 percent confidence interval, which is typically used in medical research, to the 90 percent confidence interval

which is less strict.
THE COURT: What does "two sided" mean?
THE WITNESS: Two sided means that -- you imagine a bell curve, right. So two sided means both sides are being considered; that it's a possibility that things can turn out better on this side -- I'm sorry. Well, whichever way you look at it. There's a lower range, things might actually turn out better, and then there's a higher range, which means things might actually turn out worse.
So what's typically done in research is a two-sided 95 percent confidence interval because that's why we're doing the research in the first place. Is it better or is it worse? Because if we knew the answer, we wouldn't have to do the research.
So when they changed the protocol, they only looked at one side, the 90 percent, which, again, is a less strict form of looking at the data.
BY MR. SLATER:
Q. Okay. Now, what I'd like to do is -- and, Your Honor, just to save time, can I approach and just

find an exhibit for Dr. Weber in that stack?
THE COURT: Charles will find it.
MR. SLATER: It's one that was used yesterday, the TVM study.
THE COURT: Or we can pass them all down to you and you can find it.
MR. SLATER: Awesome. Thanks, Charles.
The next one is the French TVM study. I assume you guys still have it.
(Pause.)
BY MR. SLATER:
Q. Okay. Doctor, what I've handed you is Exhibit P-49. You're familiar with this document?
A. Yes, I am.
Q. And have you relied on this?
A. Yes.
Q. What is it?
A. This is the study report that was generated by Ethicon to represent the data analysis up to and including the 12-month data from the French TVM study.
Q. Okay. On Page 3 there's a discussion of inclusion criteria. Can you explain to the jury what that means?

A. Right. So when you design a study, you want to set out at the very beginning to decide who you're going to study. Obviously, you're not going to just take all comers. You want women to be reasonably similar in their problem so that when you apply the treatment, you have some reliability in your results. So the protocol was written to include only women with advanced stage prolapse, so Stage III and IV prolapse, that was symptomatic.

Q. On Page 40 there's a discussion of protocol deviations. Can you explain to the jury what that means?

A. Right. So protocol deviations are when the protocol isn't followed. Somebody made a mistake. Something happened that wasn't according to the protocol. And so in research terms that's called a "protocol deviation."

Q. With regard to the inclusion criteria, is there a discussion here of any deviations?

A. Yes.

Q. Can you explain to the jury what the study report states?

A. There was a protocol deviation in that a substantial number of women with Stage II prolapse, which is a relatively early stage prolapse, were

included in the study, and that was 16.4 percent, which I said is a substantial number.

Q. Why, if at all, is that significant here?

A. We know from other literature that women with early stage prolapse have better results when they're surgically treated. And that makes sense intuitively; that if you're at an earlier stage, things can be caught and the surgery works better. And with Stage III and IV, women have outcomes that are not as good. So by including women who had this earlier form of prolapse, they're actually steering the results to overall look more positive.

Q. Now, in terms of the overall data that was returned here, do you have an opinion as to whether that was significant?

A. Yes.

Q. And is that for the reason you just explained?

A. Yes.

Q. Now, how did they measure prolapse and whether there was a prolapse recurrence per the study protocol? What was the method they used?

A. The prolapse was measured using a system called POP-Q. POP is for pelvic organ prolapse, and Q is for quantification.

Q. And if you could, just give the jury a little

explanation of what that means. What's done -- are you familiar with that?

A. Yes.

Q. Did you use it in your practice?

A. Yes.

Q. Did you use it in your research and your papers?

A. Yes.

Q. Please explain to the jury, we've heard it a few times. Let's get an understanding of what it means.

A. Okay. So the system involves identifying several points in the vagina and then their relationship to the vaginal hymen, which is close to the vaginal opening. So there are measures that are inside the vagina which have a negative number, so they're above zero. And then when the prolapse actually extends outside the hymen, then the numbers have a positive value.

Q. Doctor, let me stop you. When you're talking about measuring, what's actually happening when a doctor has a patient and is actually measuring? How is that done?

A. So it's like in the context of a pelvic exam where the woman is lying on the examining table and

her feet or her knees are up in stirrups, so the doctor is viewing the vagina. The woman is asked to bear down like as if she were having a bowel movement -- that's called the Valsalva -- to make the prolapse look at its most major extent. And then just using a sterile little ruler measuring those points on the vagina and their relation to the hymen, whether they're still inside the vagina or whether they've actually protruded outside of the vagina.

Q. Okay. Were there any issues with POP-Q measurements in this study?

A. Yes.

Q. Can you tell the jury about that?

A. Yes.

As I reviewed the data, and, again, I went through all the individual Case Report Forms myself for this data, and there were a very high number of errors in recording the POP-Q measurements. And that, you know, I know we're all human and nothing is ever perfectly 100 percent done. But the level of errors that I found, which is over 10 percent, really reflected, first of all, an error rate that would never be accepted in a study that was rigorously done.

And the other thing is that it suggested that the investigators who were performing these measurements really had a fundamental misunderstanding of the proper way to do these measurements, and this is what was the primary outcome.

Q. And how does that impact, in your opinion, on the reliability of the study?

A. I think since the primary outcome depends on these measurements, then it's unreliable.

Q. Now, in looking at the actual data, you've seen -- you've told us about the protocol deviations with the women allowed 16 percent with Stage II. You've told us about the POP-Q measurements. Even with those issues, were the rates of recurrence acceptable to you?

A. No, they weren't.

Q. And this study, there were endpoints of -- one year was the study, right?

A. One year was the primary endpoint, yes.

Q. And they did some analyses at six months?

A. Yes.

Q. Is that, in the world of clinical research, considered long term, short term? What is it considered?

A. That's extremely short term for an implant that's expected to be in the woman's body for the rest of her life.

Q. Okay.

THE COURT: Are you talking about both are short term, six months and one year?

THE WITNESS: Yes. Both of those would be considered short term.

THE COURT: Okay.

MR. SLATER: Now, the next exhibit is going to be 1754.

(Exhibit P-1754 marked for identification.)

MR. SLATER: Okay. Let's put 1754 up.

(Document displayed.)

BY MR. SLATER:

Q. Doctor, we've put up Exhibit P-1754. It's titled, French TVM Study Mesh Exposure Rates. Please tell us what information is on that chart.

A. Okay. So as I mentioned, I had reviewed all of the Case Report Forms myself, similar to what I did with the Gynemesh PS mesh study, and I found that there were substantial discrepancies between what Ethicon had reported and what I found by my review

of the Case Report Forms.

At six months, Ethicon reported a mesh exposure rate of 14.9 percent, and at that time the Case Report Forms showed 17.2 percent. At one year, Ethicon reported the rate actually dropped to 9.2 percent.

Q. How can the mesh exposure rate drop?

A. The way that happened is because Ethicon decided that a woman had -- if she had a mesh exposure and it was treated and went away by the one-year visit, it would not be counted as if it didn't happen.

Q. I think you misspoke. You had a double negative there.

A. Oh, I'm sorry.

Q. Say it again.

A. As if it didn't -- they -- they decided not to count mesh exposures that had occurred earlier before one year if the woman had been treated and the mesh exposure had gone away, so it was as if it didn't happen.

Q. Do you have an opinion, with your experience in the clinical research field, as to whether that was acceptable in this type of study?

A. That was completely unacceptable. I have never

seen anything in my long career of clinical research where this has been done.

Q. And just to make the record clear, what is mesh exposure as you use that term here?

A. Mesh exposure is what occurs when the mesh wears through or eats away at the vaginal wall. So instead of lying underneath the vaginal tissue, it actually comes to a position where it's literally exposed. So there's a raw open area in the vaginal wall where the mesh can be seen.

THE COURT: Well, what would treatment be for that condition?

THE WITNESS: Treatment typically starts out with medical treatment, estrogen in the vagina or antibiotics in the vagina. That only helps women between a third and a half of the time, and then surgical treatment is necessary. And even that is not universally successful and women sometimes need to go back for two or three or more reoperations in an attempt to correct this problem.

BY MR. SLATER:

Q. And when we talk about an operation, what is actually happening? What has to be done by a physician to remove the mesh when it's eroded

through the vagina and it's now visible or can be seen or felt?
A. So what happens is that a new incision has to be made in the vagina to bring the tissue from around the edges of the erosion. The doctor snips out the mesh that has been exposed, tries to remove as much of the damaged or dead tissue as possible, and then bring the edges of the healthy tissue back together with stitches.
Q. With regard to the 20.7 percent rate you found at one year, did you have the opportunity to see testimony from somebody in Ethicon with regard to that rate?
A. Yes.
Q. And tell the jury what that was and if that was significant to you.
A. Yes. This was confirmed by one of the Medical Affairs doctors in Ethicon as the correct rate.
Q. That was Axel Arnaud?
A. Yes.
Q. Tell us the three-year rate information you found. I don't think we went that far.
A. Yeah. So at three years, now Ethicon is reporting 14.4 percent. And what I found in the Case Report Forms, that the correct rate was

23.5 percent. So almost one in four women had experienced this complication.
Q. Now, with regard to the findings that you've told us about, based on your review of the actual data, do you have an opinion as to whether or not the French TVM study provided an acceptable risk-benefit profile for a procedure like this?
A. Yes, I have an opinion.
Q. And what's your opinion for the jury?
A. My opinion is that the risk-benefit profile was completely unacceptable.
Q. And just very briefly, just for the record, I need you to explain why.
A. Because of the very high rate of prolapse recurrence within a short-term follow-up of only one year, and we know already that prolapse recurrence only gets more frequent as time goes on, and this very high rate of complications which, again, unfortunately, we know also continues to increase with time because this is a permanent medical implant that continues to be at risk for complications for as long as the woman lives.
Q. Okay. Now I want to turn to the U.S. TVM study. So you had a bunch of doctors doing this in France and then they had three doctors doing it in

the U.S. You told that to the jury?
A. Yes.
Q. And let's put up Exhibit P-1735.
(Document displayed.)
(Exhibit P-1735 marked for identification.)
BY MR. SLATER:
Q. We have put up Exhibit 1735 titled U.S. TVM Study, Primary Endpoint. Tell the jury what this information is and why it's significant to you.
A. Yes.
So similar to the French TVM study, this -- in the U.S. protocol they had the same primary endpoint and the study was going to be considered a failure if the occurrence -- recurrence of prolapse exceeded 20 percent.
So what Ethicon reported, again using their 90 percent confidence interval, which is a less strict way of reporting that, 19.6 percent, only four-tenths lower, but they deemed this a success. Except that the correct number is actually 22.4 percent.
Q. How did that happen?
A. That happened by me reviewing all the Case Report Forms and seeing for myself exactly what had

been recorded on them.
Q. And there were additional patients with recurrences that hadn't been counted?
A. Yes.
Q. Under the 90 percent confidence interval, they originally were going to use the more rigorous one. Even under their reporting of the number of recurrences, what was the rate they come up with?
A. The rate was 21 percent.
Q. Based on your evaluation of the data, does it meet the primary endpoint?
A. No. It's a failure.
Q. By the way, were there POP-Q measurement problems in this study also?
A. Yes, there were.
Q. Was there any particular investigator where they were most prevalent?
A. Yes. They were concentrated at the site of Dr. Robinson, who became a Medical Affairs Director at Ethicon.
THE COURT: I'm not sure I heard it. "Robbins"?
THE WITNESS: Robinson.
THE COURT: Robinson. Okay. Proceed.

BY MR. SLATER:
Q. It's David Robinson?
A. Yes.
Q. So he was a doctor working as an investigator and then he later --
MS. ROBINSON: Objection.
THE COURT: Objection; leading? Sustained.
BY MR. SLATER:
Q. You mentioned that he later became a Medical Affairs Director?
A. Yes.
Q. Just explain what that means.
A. Okay. So at this point he was a doctor in practice. He was involved in this investigation as paid by Ethicon, and then at some point in the near future, he was hired by Ethicon to become one of their Medical Affairs Directors.
Q. Okay. Let's go now to -- they already have Exhibit 1737, right.
Let's go to Exhibit 1737, please.
This is 1737, titled U.S. TVM Study Mesh Exposure Rate. Please walk the jury through this.
A. Yes. So now you're getting a little familiar

with this system. So in analyzing the Case Report Forms from the U.S. study, I calculated a correct rate of the mesh exposures. What Ethicon reported at six months was 9.5 percent. The correct rate is 13.1 percent. At one year, again, the number actually dropped and was reported as 6 percent. The correct number is 15.7 percent.
At three years, they didn't report it at all. There is no report of the three-year U.S. TVM data. The correct rate at that point was 20.3 percent.
At five years, they reported 18.8 percent, and the correct rate was 27.1 percent.
Q. These mesh exposure rates, do you have an opinion as to whether or not that's acceptable?
A. Yes, I have an opinion.
Q. What's your opinion?
A. My opinion is this is absolutely unacceptable.
Q. And why is that?
A. That is because this is too high. In the literature, in Ethicon documents, referring back to previous studies where rates had been reported in the tens or the 15 percent range where they're identified as too high, this is too high. Now we're all the way up to 27 percent, and this is

unacceptable.
Q. Doctor, in front of you is an exhibit we've marked as PLT-0227.
(Exhibit PLT-0227 marked for identification.)
BY MR. SLATER:
Q. Can you tell the jury what this document is?
A. Yes. So this is a published medical article that represents the early results of a randomized trial -- remember we talked a little bit yesterday about randomized trial being the only kind of trial that you can assign cause and effect -- by Dr. Iglesia and her colleagues.
Q. And let me stop you there.
A. Okay.
Q. Is there an article that in your opinion is medically reliable and authoritative?
A. Yes.
Q. Did you rely on this article?
A. Yes.
Q. Okay. The findings of this study, are they significant to you in connection with what we've just learned about the exposure rates from the Ethicon studies?
A. Yes.

Q. Tell the jury why.
A. They're significant to me because the study designed a safety threshold in order to -- if they were seeing a particular complication, if it reached a certain point, they wanted to stop the study to avoid harming even more women. So this study protocol was designed with a safety threshold of 15 percent mesh erosion.
Q. What does that mean?
A. That means if in the course of data collection and analysis they found that more than 15 percent of women had experienced a mesh erosion, they were going to stop enrolling patients into the study.
Q. What does that mean, to stop enrolling them?
A. That means you just keep -- you don't keep adding patients on. You stop doing that operation because you've decided it's not safe for women, but you keep following the women who've already had the operation so you can find out how they do in the longer term.
Q. And what happened in this study?
A. In this study they stopped enrolling women at three months when they realized that they had exceeded their safety threshold, 15.6 percent, and they stopped enrolling patients.

Q. Okay. The next exhibit, it should be 3196. Is it up there?
A. Yes.
Q. Okay.
(Exhibit P-3196 marked for identification.)
BY MR. SLATER:
Q. Doctor, Exhibit P-3196, are you familiar with this document?
A. Yes, I am.
Q. And is it something you relied on?
A. Yes.
Q. What is this document?
A. This is a research funding agreement between Ethicon and Dr. Lucente.
MR. SLATER: Would you put that up, please? Just the front cover. We're not going to put anything else up.
(Technician complies.)
BY MR. SLATER:
Q. Just to let the jury see what it looks like.
We could see the date there. Just for the record, what was the date of this agreement?
A. The date is October 30th, 2007.
Q. Now, we know who Ethicon is, and just for the

record, who is Vincent Lucente?
A. Vincent Lucente is a gynecologist practicing in Pennsylvania who has worked as an Ethicon consultant for years and was their most important advocate in promoting other surgeons using the Prolift procedure across the country and across the world.
Q. Now, if you could explain to the jury what happened here. What is the investigator-initiated study that was funded and performed pursuant to this agreement? Take the jury through what this was.
A. So Dr. Lucente submitted a proposal to Ethicon to ask them for funding to perform an analysis and upkeep of a database that he had regarding his patients, he and the doctors in his practice, for women who had undergone the Prolift procedure. So he was asking for funding from Ethicon to keep this database maintained and then to ultimately present and publish the results of these data.
Q. And just to orient the jury, we're talking about patients that had Prolifts?
A. Yes.
Q. And what's the time frame?
A. The time frame of when the patients had undergone the Prolift?
Q. Yes. Yes.

A. Yes. So that began in 2005 and went up to 2008.
Q. Okay. Now, let's put up the next PowerPoint, the spreadsheet excerpt.
(Document displayed.)
What do we see here on this Lucente IIS database slide? What's the jury seeing?
A. So this is a little snapshot of what the database looked like. If any of you are familiar with Excel spreadsheets, that's what this was entered on. So you have a column heading, the patient number. And, again, for confidentiality reasons, the patient name is never entered into data like this, so she's assigned a number, her initial visit, her height, her weight, et cetera, the data collection for these women from their medical charts.
Q. Okay. Did you personally go through all the database data, these pages and pages, and look at it yourself, every patient?
A. Yes, I did.
Q. Okay. Let's go to the next PowerPoint slide, the database, numbers of patients.
Doctor, what are we seeing here on this slide, also entitled Lucente IIS Database?

A. This is a summary of what the database contained. So there were a total of 514 patients entered into the database. And as I mentioned, they spanned a time from August 2005 until July 2008. There was a follow-up visit that occurred at four months. Only 378 patients reached that four-month visit and 136 were lost, which means they didn't come back. And then at one year, only 134 patients came back and 380 patients were lost to follow-up.
Q. Okay. Now, Doctor, you have in front of you the next exhibit, P-3215.
A. Yes.
Q. Doctor, what is Exhibit 3215?
A. This is an e-mail that contains the content of an abstract that was to be presented at a scientific meeting.
Q. And what was the scientific meeting? And when are we talking about?
A. This was to be presented at the 2009 meeting of the International Urogynecology Association, which is -- we abbreviate that IUGA.
Q. Were you able to confirm that the text of the abstract in this e-mail between the people at Dr. Lucente's office was actually the same text in the abstract presented?

A. Yes; word for word.
Q. Okay. Now, you've gone through this and read this?
A. Yes, I have.
Q. And do you have an opinion as to whether or not -- we'll go through the details of it -- as to whether or not this abstract that presented data on these Prolift patients, whether it accurately reported that data?
A. Yes, I have an opinion.
Q. What's your opinion?
A. My opinion is that this does not accurately report the data in the database.
Q. Let's go to the next PowerPoint slide, "erosion rate at one year."
Please tell the jury what we're seeing here, Dr. Weber.
A. What I found when I analyzed the database was that 10.6 percent of women experienced a mesh erosion at or before one year. What was reported in this abstract was that it was only 2.2 percent.
Q. And you had shown us on a prior slide -- I'm not going to bring it up -- the number of women lost to follow-up. What impact does that have, in your opinion, in looking at this data and evaluating the

safety profile we're seeing?
A. It makes it extremely unreliable. What we know from other literature is that when women have a complication, they very frequently leave the original surgeon and seek care elsewhere. So that the fact that so many women did not follow up with Dr. Lucente and his partners suggests very strongly that a higher proportion of women actually experienced complications and simply did not report back to Dr. Lucente.
Q. This data difference, is that significant to you?
A. Yes.
Q. Why is that?
A. That is because this abstract as presented to doctors in the scientific and clinical community see these numbers and they are probably reassured by this; that, oh, look, the erosion is only 2.2 percent. It gives them a very misleading impression of what is actually going to happen to women.
Q. Let's go to the next slide, PowerPoint, anatomic recurrence rate, one year.
Okay. Doctor, this slide, Lucente IIS Database, I just want to say one thing. I think

I glazed over it. IIS, what does that mean?
A. Investigator-initiated study.
Q. What does that mean here? What happened?
A. So that means that Dr. Lucente went to Ethicon and proposed this study rather than the other way around. For example, the Gynemesh PS mesh studies and the TVM studies, Ethicon initiated that and signed up those doctors. In this case, Dr. Lucente went to Ethicon and requested this money.
Q. Okay. Please take us through the data on this slide about the recurrence rates.
A. Okay. Let's start at the bottom. The abstract reported that within one year, 13 percent of women had experienced a recurrence of their prolapse.
What I found was at one year when you looked at women -- well, let me explain one thing. The treated compartment, so that means -- maybe you've heard some of this terminology. In speaking to each other as doctors, we divide the vagina up into compartments. So there's the anterior compartment, the apical compartment, the top of the uterus -- the top of the vagina that may have the cervix and uterus, and then the posterior compartment, the back wall.
In this database, not everyone had

Prolift that was total, meaning it was anterior and posterior. Some of them only had an anterior; some of them only had a posterior.
So what I mean by the treated compartment means that aspect of the vagina that actually received the Prolift. So that they got an anterior Prolift, that was considered treated. And that rate was 32 percent.
So almost a third of women at one year already had recurrence of prolapse where Prolift had been implanted.
At the very top, when I considered all the compartments -- which is really what women care about. They care about whether their prolapse is gone and that no prolapse is ever going to come back -- it was practically half of women who had recurred by one year.
Q. 49.7 percent?
A. Yes.
Q. And those figures, who calculated those numbers?
A. I did.
Q. And, again, just as you had testified earlier, was there anything different you did in reviewing this data than if you were doing it for a study in

the medical community?
A. No; exactly the same.
Q. Before we go off this slide, did you have the chance to read the deposition testimony of Dr. Lucente and his partner, Dr. Murphy?
A. Yes.
Q. Did you learn anything from those depositions of significance regarding how Dr. Lucente recorded whether somebody had success or failure or whether they re-prolapsed?
A. Yes.
Q. Please tell the jury what you learned from that deposition testimony.
A. Dr. Lucente had a habit of not recording a complete POP-Q measurements. We talked about the POP-Qs. There are five points that are particularly important in determining whether a woman had prolapse or not. And he testified that he felt he could look at a woman without making measurements and decide whether or not she had recurrent prolapse.
Q. Do you have an opinion as to whether that raises any issues?
A. Yes.
Q. What is that?

A. It raises issues in the sense that that's completely unacceptable as far as a research practice, and also because we know Dr. Lucente has an extremely high financial bias related to Ethicon that he would be inclined to more favorably report the outcomes.
Q. Was Dr. Lucente involved in the Gynemesh PS study and the TVM study you've already gone through for the jury?
A. Yes, he was.
Q. What was his involvement?
A. He was an investigator.
Q. So his data would have been included in the results?
A. Yes.
Q. In the abstract, at the bottom there's an author's disclosure information. Is there anything significant about what they disclosed there?
A. Yes.
Q. Please tell the jury what that is.
A. They disclosed incorrectly that none of the authors had any disclosures worth making, which means -- disclosures mean do you have an association with anyone like a company that could potentially bias your results.

Q. What did they say here?
A. They said they had no disclosures to make, despite the fact that they are all paid Ethicon consultants.
THE COURT: All Ethicon what?
THE WITNESS: Consultants.
THE COURT: "Consultants."
BY MR. SLATER:
Q. Now, why is that an issue for people reading the study and the data?
A. It's been well established in the literature that -- which is why these disclosures are made in the first place -- that when investigators are receiving money -- that's basically the definition of a financial bias -- that they are inclined to record things more favorably which includes more favorably good outcomes and minimizing bad outcomes or complications.
Q. Based on your review of all the medical literature and the documents in this case, did Ethicon rely, to any extent, on Dr. Lucente's literature and his reports of results with Prolift patients?
A. Yes, absolutely.
Q. Did Dr. Lucente ever report complication or

recurrence rates like what you found when you went through his data yourself?
A. No.
Q. Can you characterize the difference?
A. The difference is that he never reported anything resembling this. And as you saw just by this one example in this abstract, reporting results that are far more favorable to the Prolift than what actually occurred, even to the extent of reporting in a series of 350 patients that no mesh exposures had occurred at all.
Now, we know that it occurs in at least 10 percent of women, at least. 350 patients, no exposures. And in response to that, one of Ethicon's medical directors replied: Who believes Dr. Lucente's group --
MS. ROBINSON: Objection. Nonresponsive. Move to strike.
THE COURT: Overruled. Continue.
THE WITNESS: Who believes Dr. Lucente's group when they report zero erosions? Nobody.
BY MR. SLATER:
Q. Now, based on your review of the Gynemesh PS

study data, the TVM study data, and Dr. Lucente's IIS reported data, do you have an opinion as to whether or not all that data together presents an acceptable or an unacceptable risk-benefit profile for this procedure?
A. Yes, I have an opinion.
Q. Please tell the jury your opinion.
A. I have the opinion that it is absolutely unacceptable in terms of a risk-benefit profile.
Q. And just for the record, is that for the reasons you've explained with regard to the other studies as well?
A. Yes.
Q. Okay. Let's go to the next document. It's in front of you. And it's been -- we'll just put the front page up. It's Exhibit P-2137. This is the Clinical Expert Report signed January 14, 2005.
A. Yes.
Q. Are you familiar with this document?
A. Yes.
Q. Have you read it and reviewed all of the references and the information in it?
A. Yes.
(Exhibit P-2137 marked for identification.)

BY MR. SLATER:
Q. Doctor, having reviewed this, do you have an opinion as to whether or not this Clinical Expert Report is sufficient to establish that there was clinical evidence demonstrating the Prolift was safe and effective and could be marketed on a widespread basis as it was?
A. Yes, I have an opinion.
Q. Please tell the jury your opinion.
A. My opinion is that this Clinical Expert Report does not contain sufficient information to conclude that the Prolift was safe and effective and should be marketed on a widespread basis.
Q. Doctor, at the end of the report it talks about "contraction." And that's on the last page.
A. Yes.
Q. And what is ultimately the conclusion about contraction in this report?
A. The conclusion is there were no instances of tissue contraction reported in the Gynecare Gynemesh clinical evaluation.
Q. And what did that lead the -- how did that drive the conclusion in this report?
A. That led to the conclusion that the use of the Prolift pelvic floor repair kits for the purpose of

pelvic floor repair appears to be safe and effective -- efficacious.
Q. You mentioned this before, but in this context, the Gynemesh PS study, did that serve as an adequate basis to evaluate mesh contraction?
A. No.
Q. Why not?
A. Remember we talked, they didn't even have a space on the Case Report Form to record whether or not mesh contraction had occurred.
Q. At this time in January of 2005, was there published literature by the TVM group regarding retraction?
A. Yes.
Q. And was that significant to you in this?
A. Yes.
Q. And what was the message of that published literature?
A. The message was that the mesh contraction is a very worrying complication, impossible to predict in terms of in which women this is going to occur to a severe degree, and is something that needs to be further studied in order to reduce this occurrence to make this a safe product.
Q. If the available clinical evidence and medical

literature had been evaluated in the way that you believe it should have been, what do you believe the appropriate conclusion would have been in this Clinical Expert Report?
A. The appropriate conclusion should have been that Prolift was in no way safe and effective and should never have been marketed.
Q. Okay.
MR. SLATER: We can take that down.
(Technician complies.)
BY MR. SLATER:
Q. Doctor, we have up here a PowerPoint slide used by the defense in opening statements. You've seen this?
A. Yes.
Q. I'd like to ask you about the Prolift, where they say a 16.7 percent of new onset dyspareunia. Do you have an opinion as to whether or not that is an accurate representation?
A. Yes, I have an opinion.
Q. What's your opinion?
A. My opinion is that that is not accurate at all.
Q. Why do you say that? What's the basis of that opinion?
A. The basis of that opinion is my review of the

article from which this was drawn and a careful analysis of the information presented in that article.

Q. And take the jury through what, in your opinion, the appropriate number should be here.

A. The appropriate number of women with new onset dyspareunia after the Prolift procedure was 39 percent.

Q. And why do you say that?

A. I say that because that's what was reported in this article based on questionnaire results where the women themselves were asked --

MS. ROBINSON: Objection.

THE COURT: Legal basis?

MS. ROBINSON: May we approach?

THE COURT: Sure.

- - -

(The following discussion transpired at sidebar out of the hearing of the jury:)

- - -

THE COURT: Legal basis for the objection?

MS. ROBINSON: Your Honor --

THE COURT: What is the legal basis for the objection?

MS. ROBINSON: Your Honor, this expert was never disclosed on the fact that she was going to be assessing and evaluating the Lowman article and offering an opinion that it was improper.

THE COURT: The Lowman article is not contained in all 500 pages?

MR. SLATER: It's clearly discussed in the reports.

THE COURT: I'm sorry.

MR. SLATER: I'm sorry, Judge.

THE COURT: Do you want to talk?

MR. SLATER: I'm sorry, Judge.

THE COURT: Please talk to each other.

(Whereupon an off-the-record discussion was held.)

(Pause in the proceedings.)

THE COURT: We'll take a ten-minute recess.

I'll see counsel in chambers.

(Sidebar discussion paused.)

(The following transpired in open court in the presence of the jury:)

- - -

COURT CRIER: Please remain seated until the jury has left the courtroom.

Jurors, please turn your clipboards, and watch your step.

- - -

(Whereupon the jury exited the courtroom at 11:04 a.m.)

- - -

(The following discussion transpired in chambers, out of the hearing of the jury:)

THE COURT: Okay. This article was not referenced in any of the 500-plus pages of her disclosure; is that what you're telling me?

MS. ROBINSON: The article itself is. But the fact that she's going to reanalyze the data in that article was not.

THE COURT: Okay. Was defense ever put on notice in any of the 5-, 6-, 700 pages that this witness has disclosed in this total litigation that some reanalysis of this article was involved or was done?

MR. SLATER: A specific intent to reanalyze the article was not discussed. What she did in the report was she discussed a massive amount of literature. She talked about

the fact that it does not represent an adequate or acceptable risk-benefit profile. So they're certainly on notice that with regard to any of the articles in the report, she could take the article and explain what it showed and why that enters into her opinions.

THE COURT: Okay. But nowhere in all the -- how many pages was disclosed in this whole litigation from this witness?

MR. SLATER: I'd have to estimate, probably 7- or 800 pages.

THE COURT: Okay. In none of the 800 pages did she disclose a reanalysis of the Lowman article that she had done; is that accurate?

MR. SLATER: Never in those terms. I don't consider this a reanalysis, though, Judge. I just consider it her telling what the data shows.

THE COURT: Read back the question that was objected to.

- - -

(Whereupon the court reporter read back from the record as follows:

"Question: And why do you say that?

"Question: And take the jury through what, in your opinion, the appropriate number should be here.")

- - -

(Whereupon an off-the-record discussion was held.)

- - -

THE COURT: Wait. Let's do it differently.

Put on the record the question you're going to ask her about the Lowman -- first off, tell me what the Lowman article is.

MR. SLATER: The defense expert -- one of their two experts is someone named Dr. Joye Lowman. When she was a Fellow, she wrote an article, along with some other people, where they stated in the article that the dyspareunia rate was 16.7 percent.

THE COURT: Okay.

MR. SLATER: If you go through the article and you just read the numbers of patients and what they reported, you can add them up for yourself and you'll come to different numbers. And that's all she's doing. And what happened was --

THE COURT: Hold on. Wait a minute.

And when was this Lowman article published, in relation to when the product went on the market?

MR. SLATER: Around 2007, I think.

THE COURT: No. That doesn't help me.

MR. SLATER: Oh. The product went on the market in '05.

THE COURT: So like two years roughly after it was on the market.

MR. SLATER: Right.

THE COURT: And is Lowman a witness you're going to call?

MS. ROBINSON: She is, Your Honor.

THE COURT: Was Lowman referenced in the 700 pages?

MR. SLATER: Definitely. The article is referenced. And what we're responding to now, frankly, is a slide that was put up in front of the jury. And obviously I didn't know they were going to put the slide up. And she's just taking the jury through whether the slide is accurate. And all she's doing is telling what the numbers are per the article.

THE COURT: Okay. Got it.

Yes. Anything further? Is there anything further?

MS. ROBINSON: No, Your Honor.

THE COURT: Okay. The objection is overruled.

Let's take a break.

MR. SLATER: Yes, Your Honor.

MR. MORIARTY: Your Honor, you at one point last week asked for the transcripts of the videos that had been played.

THE COURT: Yeah. Do we have it?

MR. MORIARTY: Here. (Indicating.)

So sorry it took so long. There was some technical difficulties getting the bigger...

THE COURT: Fine. Thank you.

(Sidebar discussion concluded.)

- - -

(Whereupon a recess was taken.)

- - -

COURT CRIER: Please remain seated until the jury reaches the jury box.

(Whereupon the jury entered the courtroom at 11:13 a.m.)

(The following transpired in open court in the presence of the jury:)

- - -

COURT CRIER: Court is back in session.

THE COURT: Next question, please.

BY MR. SLATER:

Q. Okay. Doctor, just briefly tell us why you said 39 percent would be the appropriate rate there based on the study that number came from.

A. Yes. When I examined the data reported in this article, the questionnaire results showed that 39 percent of women experienced new dyspareunia, pain with sex, after the Prolift insertion.

The 16.7 percent comes from a chart review that the authors decided to do instead of relying on the patient's questionnaires. So a chart review, as you may know, is where they just look back and see what the doctors have recorded. And they chose to rely on the chart review rather than on the questionnaires that the patients filled out themselves.

Q. And in this context, what is your assessment of that decision?

A. My assessment of that decision is that it

minimized what the women were reporting regarding their problems they were having with sex.
Q. Okay. We could take that down.
The next, Doctor, in front of you is an Exhibit PLT-0629.
A. Okay.
Q. And this is a -- well, what is this document? Very simply, what is the document?
A. This is an abstract from the TVM group reporting on a group of patients who had undergone the TVM procedure that was before the Ethicon-funded studies of the TVM that we've already looked at this morning.
Q. Is this medically reliable and authoritative?
A. Yes.
Q. Is it something you relied on?
A. Yes.
Q. Okay. Let's go to the next exhibit, PLT-0089.
(Exhibit PLT-0089 marked for identification.)
BY MR. SLATER:
Q. Very simply, what is this document?
A. This is a published medical article from the TVM group, the French doctors, who are again reporting on a group of the patients who underwent

the TVM procedure before the Ethicon-funded TVM studies. And in this study they were looking at safety.
Q. With regard to the -- well, first of all, is this article medically reliable and authoritative?
A. Yes.
Q. Did you rely on it?
A. Yes.
Q. What information, if any, was significant to you regarding complications and safety at the 3.6 months point this is looking at?
A. What was significant to me, that at this extremely short duration of follow-up of only about three and a half months, they were reporting a high frequency of complications.
Q. And I think it might be in the abstract -- you can find it -- what was the overall postsurgical complication rate at 3.6 months?
A. Okay. 33.6 percent.
Q. Do you have an opinion as to whether that is acceptable, concerning, anything like that?
A. Yes. My opinion is that that's very concerning, again, as I mentioned, at that very low duration of follow-up and an extremely high rate of complications.

Q. And the short follow-up of 3.6 months, why is that significant here?
A. It's significant because, as we know, the experience of complications is only going to increase as time goes by.
Q. Okay. Let's go to the next one, P-1499.
(Exhibit P-1499 marked for identification.)
BY MR. SLATER:
Q. Are you familiar with this document?
A. Yes.
Q. What is this?
A. This is an abstract from the French TVM doctors reporting their preliminary results of the Prolift technique.
Q. How many patients are they talking about here?
A. 110 patients.
Q. Is this medically reliable and authoritative?
A. Yes.
Q. Did you rely on this?
A. Yes.
Q. And it's very small type at the top left. This was presented in Athens, Greece in September 2006?
A. Yes.
Q. Okay. What, if anything, is significant about

this presentation by the TVM group in September 2006?
A. It's significant to me that, again, in this very short range of follow-up, they were reporting a significant number of complications. And they found that related to that, they needed to assess more precisely functional and sexual outcomes before to extend the indications of Prolift to young women or to primary prolapse repair.
Q. Let's just stop there. Let the siren go.
A. Yes.
(Sirens outside courtroom.)
(Pause.)
Q. Can you explain to the jury why that's significant to you?
A. Yes.
So these are the doctors who are developing -- have been developing this technique; and what they're seeing at this short duration of follow-up is enough to concern them where they need more information about the functional and sexual outcomes of women before this product is introduced in a widespread manner, and particularly for young women, in part related to the sexual activity and in part related to increasing the length of time that

these women would carry the permanent implant and to primary prolapse repair, which means the first time the prolapse is fixed.

Q. And with regard to the Prolift and how the Prolift was indicated and marketed, is there a difference there?

A. Yes.

Q. And what is that difference?

A. The difference is that Prolift was marketed for almost all patients.

Q. Do you have an opinion as to whether that was appropriate?

A. Yes, I do.

Q. And what's your opinion?

A. My opinion is that that was absolutely inappropriate.

Q. And I want to go to the next document and talk a little more about this, P-2640.

A. Yes.

Q. Is this a document you are familiar with and relied on?

A. Yes.

Q. What is this document?

A. This document is a set of PowerPoint slides from a meeting of the TVM group that was held in

Paris on September 29, 2003.

Q. And if you turn within it, there's a page on key subject requirements. Is there something of significance there?

A. Yes.

Q. What are they telling here about the requirements for who they were saying should be in the TVM study and operated on by this procedure?

A. Most importantly, they required that women have Stage III or IV advanced prolapse, advanced stage prolapse, that was symptomatic.

Q. What does that mean?

A. That means they were reserving the use of the Prolift or the TVM technique for women who had these advanced stages who were symptomatic, not for women with early stage prolapse.

Q. And, again, do you have an opinion as to whether or not the indications for the Prolift were appropriate or not, based on the literature you've talked about here?

A. Yes.

Q. What's that opinion?

A. My opinion is that it was not appropriate in terms of extending or marketing the Prolift product to all -- almost all women.

Q. If it was going to be on the market, which we know you've already given an opinion to the contrary, but if it was going to be on the market, how should it have been indicated?

A. It should have been indicated for women who had no other options, who had advanced degree prolapse that was not able to be successfully treated with other types of surgery who had gone through other types of surgery and still had this recurrence. And, in fact, this is what professional organizations have belatedly come to realize as far as the very narrow indications that should exist for mesh use in prolapse surgery.

Q. Doctor, the next document, PLT-0489, are you familiar with that document?

A. Yes.

Q. Very briefly, what is this?

A. This is a published medical article that studies women after they have had the Prolift placed and studies them by using an ultrasound to look at the permanent mesh implant.

Q. Is this article, in your opinion, medically reliable and authoritative?

A. Yes.

Q. Did you rely on it?

A. Yes.

Q. And the authors of this, who were the people who treated these patients?

A. These are members of the French TVM group.

Q. The last name there, Jacquetin.

A. Yes.

Q. That's Professor Jacquetin?

A. Uh-huh.

Q. With regard to this study which studied with ultrasounds what happened in the body, what is of significance to you?

A. What is of significance to me is the extremely high proportion of women who experienced mesh retraction that they could identify by ultrasound.

Q. And what were those figures?

A. 89 percent of women who had anterior Prolift had moderate to severe retraction.

Q. Doctor, when they were measuring what retraction is -- first of all, just to ground us, what is retraction that you're discussing here?

A. Retraction, mesh retraction or contraction -- those terms are used interchangeably -- is when in the course of healing the tissue begins to shrink and the mesh is drawn along with it. So that instead of laying flat and occupying the space that

it was intended to occupy, it instead retracts literally. It becomes a smaller area. It becomes crunched up, bunched up. The mesh can become folded on itself. So that's what mesh retraction represents.

Q. You mentioned "bunching." How does bunching relate to retraction?

A. Yes. So you can just kind of imagine in your minds this what should be a flat piece of mesh. As it's undergoing the process of retraction, the substance of the mesh has to go somewhere, so it becomes wavy and folded and bunched so that it's -- it's laying over itself. It's not a single flat layer.

Q. When the mesh originally goes into the body, does it go in flat?

A. No, it does not.

Q. And if they're bunching or uneven shaping to the mesh, what impact does that have on contraction?

A. That simply accelerates the process of contraction.

Q. Was Ethicon aware of this from the beginning?

A. Yes.

Q. Now, with regard to this study -- so what did they do? They did ultrasounds. And what did they

see?

A. Yes, they did ultrasounds of the mesh implant. And what they found was exactly what we've been talking about. They could see the mesh folds. They could see what they described as an undulation, a waviness, a wavy appearance of the mesh, very dramatic thickening of the mesh instead of that thinness as it went in. Instead it was thickened, which represents not only the folding and the waviness, but also the scar tissue that builds up that occurs around the mesh itself.

Q. Is that known as scar plating or bridging fibrosis?

A. Yes.

Q. What's the clinical impact of that?

A. Very severe. This distorts the vagina. This causes pain. Remember that the anterior Prolift implant has those four arms that go out through the muscles and tissues of the groin. So that as the mesh, the body of the mesh implant is contracting, that's dragging on those mesh arms. They can't move because they're fixed in the tissue. So that contraction that's going on in the body of the mesh drags on those mesh arms, creates pain there in the muscles of the hip and thigh which just causes

symptoms related to physical activity, obviously with vaginal anatomic distortion, but contraction also leads to a higher risk of erosions and recurrent prolapse. Women have, as you can easily imagine, terrific difficulties with sex, and that's the whole picture.

Q. Doctor, the next exhibit in front of you is P-1706.

A. Yes.

Q. Are you familiar with this document?

A. Yes.

Q. Did you rely on this?

A. Yes.

Q. Is it medically reliable and authoritative, in your opinion?

A. Yes.

Q. What is this document?

A. This represents a presentation, a slide set of presentations that were made at the International Urogynecology Association meeting.

Q. And it says June of 2009?

A. Yes.

Q. Is there a relationship between this document and the study you just told the jury about?

A. Yes.

Q. What is that relationship?

A. These are the same authors. These represent the same patients that we talked about in that ultrasound article.

Q. And what did they say in this presentation regarding the clinical impact of mesh shrinkage? There's a page -- about 14 pages in that I think discusses that.

What of significance to you, most significant with regard to what you just told the jury about the mesh shrinkage?

A. They found that almost 20 percent of women, 19.6 percent of women, had tenderness and pain on vaginal examination associated with the mesh shrinkage with an average pain score of 5 out of 10.

Q. Is that significant to you?

A. Yes.

Q. Why?

A. Because this is the clinical effect of the mesh contraction that we were just talking about a minute ago. You might be familiar with a pain scale where it starts at zero when you have no pain at all, and 10 is the worst pain that you've ever experienced in your life. So this is an average of 5. Five is moderately severe pain. This is not mild, you know,

something that you might be able to live with. This is a serious level of pain that's occurring in 20 percent of these women. One in five of these women have this level of severity of pain.

Q. Doctor, with regard to all the literature and the studies and the medical issues you've discussed with the jury today, do you have an overall opinion about whether or not the risk-benefit profile for the Prolift was acceptable?

A. Yes, I do.

Q. What is your opinion?

A. My opinion is that the Prolift has a completely unacceptable risk-benefit profile.

Q. And is it for all the reasons you've explained to the jury today?

A. Yes.

Q. Let's go to the next exhibit, PLT-151.

(Exhibit PLT-0151 marked for identification.)

THE WITNESS: I believe it's 0151.

MR. SLATER: 0151.

I might have given the extra copy.

BY MR. SLATER:

Q. Doctor, is that an article you're familiar with?

A. Yes.

Q. Is it medically reliable and authoritative, in your opinion?

A. Yes.

Q. Have you relied on it?

A. Yes.

Q. Just tell the jury simply what it is.

A. So this is a published medical article that is called a systematic review. What these authors did is search through all of the medical literature for articles that were relevant to this topic. And this is complications and reoperation rates after vaginal surgical repair of prolapse. And so they took all the articles from the literature and combined the data to come up with an overall summary of what the literature shows.

Q. And what, if any, significance -- what was significant to you about that?

A. This was significant to me because in the way that they presented it, they divided the women up into three groups where the kind of surgery they underwent was either traditional suture procedures or an abdominal sacrocolpopexy, which is an abdominal way to fix prolapse, and mesh. Mesh kits, I should say.

Q. And what's the most important finding from your perspective?

A. The most important finding was that the complications and reoperation rate was highest in the group of women who had undergone the mesh kits, even though they had the shortest duration of follow-up. And as we've already talked about this morning, the longer you study women or the longer they go through their lives, they're going to -- the frequency of complications is only going to increase.

So the fact that a duration of follow-up that was significantly shorter than for the other two groups of women, the complication rates were so much higher and reoperation rates were so much higher than those other two groups, it's only going to get higher as time continues to go on.

Q. And is that significant to you?

A. Yes.

Q. And is that one of the bases for the opinion you've just offered us regarding the Prolift?

A. Yes.

Q. Okay. Doctor, let's go to the next exhibit, PLT-0011.

Can you tell the jury what this

document is, please?

A. This document is a Practice Bulletin that was published by the American College of Obstetricians and Gynecologists which is the professional organization that represents OB/GYN doctors. The OB/GYN doctors are members of this professional organization. And so what they do from time to time is issue these Practice Bulletins which is a summary of the current available information to provide clinicians with an update. Busy clinicians don't read all of the literature all of the time, so this is provided as a way for them to be aware of what's currently going on without having to do all the literature reading themselves.

Q. All right. Let me stop you there. Is this medically reliable and authoritative, in your opinion?

A. Yes.

Q. Is it something you relied on?

A. Yes.

Q. What was your involvement in this?

A. I wrote this.

Q. And when was it published?

A. It was published in February 2007.

Q. And how is it that you came to be asked to

author this?
A. The committee on Practice Bulletins Gynecology invited me to take a rough draft that had been produced by my coauthor who's named on the title here, Scott Smilen, who's also a urogynecologist, to take a rough draft that he had produced but he had been unable to finish, take that and complete the project to come up with the final finished bulletin.
Q. Now, one thing, when you published this, had you ever spoken to me?
A. No.
Q. Okay. Now, what I'd like to focus on is on Page 468.
Your Honor, as Dr. Weber is the author, is it okay if we publish this?
THE COURT: Yes.
MR. SLATER: Thank you.
Put this up. Start with the cover first just to orient the jury so they could see what it looks like.
(Document displayed.)
MR. SLATER: Okay. That's the cover. And we're going to go to Page 468, the top right corner, the first full paragraph.
Okay.

BY MR. SLATER:
Q. What I'll ask you to do, Doctor, you wrote it, can you just tell the jury what you wrote there. Can you just read it for the jury?
A. Yes.
"Given the limited data and frequent changes in the marketed products, particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion, the procedures should be considered experimental and patients should consent to surgery with that understanding."
Q. Why did you say that?
A. I said that because at that point in time -- at that point in time there wasn't enough information for women to be adequately counseled about what they could expect. Remember we talked earlier about whenever you're making a decision or, you know, a doctor might recommend something to you and you talk about what that means, what are the possible ways that it could work well for me, what are the possible ways it can do badly for me or hurt me. And there simply wasn't enough information at that point to have -- to adequately counsel women to be

able to tell them, okay, this is what you can expect, and then the woman can take in that information and decide, okay, is this a good thing for me or is this not a good thing for me.
Q. What is the significance of a procedure -- and would the Prolift fall within this category?
A. Yes.
Q. What's the significance of a procedure like the Prolift being experimental? In the real world, what's that mean?
A. Well, what that means is that it shouldn't be used outside of a research setting where the women are clearly understanding that they're voluntarily participating in a study. Remember we talked about this a little earlier. If you already knew the answer to the question, you wouldn't have to do the study. But since the information isn't there, isn't sufficient, if it's not enough, then to get the information, women need to be studied. But they do that in a voluntary capacity. And there's a whole separate consent because, of course, experimenting on people without their permission is unethical.
Q. What factually happened after this was published?
THE COURT: I'm sorry, when was it

published?
THE WITNESS: It was published in February of 2007.
MR. SLATER: Thank you, Judge.
BY MR. SLATER:
Q. What factually, as a matter of fact, what occurred as a result of this publication? What was part of the reaction that is significant to you?
A. A small number of members of the American College complained about the wording of experimental.
Q. And what's your understanding as to why that occurred?
MS. ROBINSON: Objection.
THE COURT: Sustained.
BY MR. SLATER:
Q. Do you know why that happened?
A. Yes, I do.
Q. Why did it happen?
MS. ROBINSON: Objection.
THE COURT: Sustained.
BY MR. SLATER:
Q. Was there a change made to the word --
A. Yes.
Q. -- "experimental"?

Why was that change made?
MS. ROBINSON: Objection.
THE COURT: Sustained.
BY MR. SLATER:
Q. Do you know why the word "experimental" was changed, as a matter of fact?
MS. ROBINSON: Objection.
THE WITNESS: Yes, I do.
THE COURT: Sustained.
I think we've covered all the ways you can put that same question.
Next question.
BY MR. SLATER:
Q. Doctor, after the word was changed, did you -- well, let's go to Exhibit PLT-0506, the next exhibit.
What is PLT-0506?
A. This is a letter that I -- that was published in the literature that I wrote to the editor of the International Urogynecology Journal in response to --
MS. ROBINSON: Objection.
THE COURT: Overruled.
Continue.
THE WITNESS: Thank you.

An article that was written by two doctors, a urogynecologist and a medical ethical specialist, Drs. Wall and Dr. Brown, in their article which was entitled, Commercial Pressures and Professional Ethics, Troubling Revisions to the Recent ACOG Practice Bulletins on Surgery for Pelvic Organ Prolapse.
THE COURT: Okay. I'm a little bit lost.
Is this what was put up on the screen an article that you wrote?
THE WITNESS: I'm responding to an article that Drs. Wall and Brown wrote. And this is -- the title is --
THE COURT: Okay. Whatever was put up on the screen, whatever number that is, you wrote it?
THE WITNESS: Yes.
THE COURT: Okay. And was it published anywhere?
THE WITNESS: Yes.
THE COURT: Where was it published?
THE WITNESS: It was published in the International Urogynecology Journal.
THE COURT: Okay. So could this

properly be characterized as a conversation that's going on in some scientific or medical community?
THE WITNESS: Uhmm, personally, I think "conversation" may be informal, considering this is published in the medical literature.
THE COURT: Okay. What would you call it?
THE WITNESS: I would call it a -- a debate.
THE COURT: Okay. Fair enough.
Do you have an objection?
MS. ROBINSON: I do, Your Honor.
THE COURT: Overruled.
You may proceed with this article.
MR. SLATER: Thank you, Your Honor.
BY MR. SLATER:
Q. So did you write what's on the board, PLT-0506?
A. Yes, I did.
Q. And it says published September 25, 2009?
A. Yes.
Q. And you had actually submitted it in August of '09?
A. Yes.

Q. And does this represent what occurred and what your viewpoint on that is?
A. Yes.
Q. Please tell the jury, you can read it to the jury, what you stated, if that fully states or sets forth your opinions and view on this.
THE COURT: How about you just tell them without reading it.
THE WITNESS: All right.
This letter represents -- this letter represents what I was told at the time ACOG was making the change in the wording of the original Practice Bulletin, which was over my objections.
MS. ROBINSON: Objection, Your Honor.
THE COURT: Is that what you said there? I was told this stuff and therefore...
THE WITNESS: Yes.
THE COURT: Okay. Overruled.
THE WITNESS: I was told by the staff member from ACOG representing the committee on Practice Bulletins Gynecology that the real reason for the change was because physicians were concerned that something labeled experimental, A, wouldn't be covered by insurance. And, B, would expose them to

medical/legal risk if a complication occurred in the course of these procedures that were labeled "experimental."

Now, I felt that that was something that should be seen as a red flag by the organization, the American College, that these clinicians were not concerned about patient safety. They were concerned about what protected their income. And I felt that if ACOG truly was going to stand behind its promise to women as they state in their bylaws, to provide the highest quality of care for women and to maintain the highest standards of clinical practice, then they would not have made this change.

Another explanation for why this change was made was that --

THE COURT: Is that in your article?

THE WITNESS: Yes.

THE COURT: Okay. Keep going.

THE WITNESS: -- that ACOG claimed that the meaning of the word "experimental" was not clear to people.

Whether or not that was true, if ACOG felt that way, they could have added a

clarification to the document itself as far as exactly what was meant; or they could have adopted an official definition of the term "experimental," as other professional organizations have done, like the American Society for Reproductive Medicine.

The fact that they didn't do either of these two things underscores their real motivation for why the wording in the bulletin was changed.

BY MR. SLATER:

Q. As you stand here now, do you have an opinion as to whether or not these mesh kits like the Prolift should have been deemed experimental, as you wrote in the published article?

A. Yes, I do.

Q. And what's your opinion?

A. My opinion is that if they were to be used at all, they should only have been used in the context of an experimental study where women gave their permission to be voluntarily experimented on.

Q. And based on your review of the internal documents and the medical literature and all of the information you have with regard to the Prolift and what happened going forward from '07, do you still

hold that opinion now?

A. Yes, I do.

Q. Do you have an opinion as to whether or not your decision to describe these kits as experimental was correct, based on that?

A. Yes, it was.

MR. SLATER: Thank you, Your Honor.

THE COURT: Oh, are you finished?

MR. SLATER: I am finished.

THE COURT: Terrific.

Cross-examine.

MR. ISMAIL: Time to readjust, Your Honor.

THE COURT: Do we need to send the jury out?

MS. ROBINSON: It would probably be helpful.

MR. SLATER: I used to deliver Sheetrock. I'll get it out of the way.

THE COURT: Charles, we'll take a ten-minute recess.

COURT CRIER: Yes.

Please remain seated until the jury has left the courtroom.

Jurors, turn your clipboards over,

please. Watch your step, please.

- - -

(Whereupon the jury exited the courtroom at 11:45 a.m.)

- - -

(Whereupon a recess was taken.)

- - -

COURT CRIER: Please remain seated as the jury enters the courtroom.

- - -

(Whereupon the jury entered the courtroom at 11:58 a.m.)

- - -

COURT CRIER: This court is back in session.

THE COURT: Counsel, we're going to go about a half an hour.

MS. ROBINSON: Thank you, Your Honor.

- - -

CROSS-EXAMINATION

- - -

BY MS. ROBINSON:

Q. I guess it's almost good afternoon again.

Good afternoon, Ms. Weber. I want to talk to you a little bit further today about your

background.
You are not a licensed Medical Doctor; is that correct?
A. Yes.
Q. And you are not licensed in any state, correct?
A. Yes.
Q. And you haven't been licensed since, what, approximately 19 -- or I'm sorry, 2008?
A. Approximately.
Q. You are not currently on any staff at any hospitals; is that also correct?
A. Yes.
Q. You are not board certified today, correct?
A. I am board certified.
Q. Do you currently hold a current certificate as a practicing member of the Obstetrics and Gynecology Society?
A. I am not practicing clinically, yes, that's true.
Q. You are not and never have been certified as a specialist in female pelvic reconstructive surgery; is that correct?
A. Yes.
Q. And you have not attended any continuing medical courses since you gave up your license; is

that correct?
A. Yes.
Q. Is it also correct that you have not examined a patient since the end of 2006?
A. Yes.
Q. Is it also fair to say you haven't provided any consultation to any patient since that time --
A. Yes.
Q. -- in their care and treatment, right?
Okay. So I also want to ask you a few questions now about your experience with Prolift. You haven't performed a Prolift surgery, correct?
A. That's right.
Q. In fact, you quit performing surgeries in 2004, right?
A. That's right.
Q. And that was before Prolift became [sic] on the market?
A. Yes.
Q. You had never implanted Prolift in a cadaver?
A. That's correct.
Q. You've never attended any professional education courses in Prolift, correct?
A. Yes.

THE COURT: Yes, that's correct; is that what you mean?
THE WITNESS: Yes.
THE COURT: Yes. Okay.
BY MS. ROBINSON:
Q. You've never treated a woman who had a Prolift, correct?
A. That's correct.
Q. You've never examined a woman who had a Prolift, correct?
A. That's right.
Q. Prior to being retained as an expert in this litigation, you had never seen a surgical video of the Prolift surgery, correct?
A. That's right.
Q. And also prior to being retained in this litigation, you had never observed a Prolift surgery with another surgeon; is that correct?
A. Yes.
Q. In fact, have you ever observed a Prolift surgery with another physician?
A. No.
Q. Before being engaged as an expert in this litigation, you had not read the Prolift Instructions For Use; is that correct?

A. Yes.
Q. And you had also not reviewed -- you had not participated in any clinical trials involving Prolift, correct?
A. Yes, that's right.
Q. Now, you're testifying here today as a paid expert, correct?
A. Yes.
Q. I believe you estimated yesterday that you reviewed over a million records?
A. Yes.
Q. And you testified also yesterday, I believe, that you began working with Mr. Slater in 2010; is that correct?
A. Yes.
Q. What time in 2010 did you start working with him?
A. February.
Q. You also mentioned yesterday that you were mentoring some medical students?
A. Yes.
Q. Does that involve the care and treatment of any patients?
A. No.
Q. Are you being paid for that position?

A. No.
Q. You're testifying here today at a thousand dollars a day -- or an hour, correct?
A. Yes, that's right.
Q. Yesterday I believe you mentioned that you also write some?
A. Yes.
Q. Have you published any medical literature since 2007?
A. I have a commentary that has been submitted for publication. It has not yet been published.
Q. So fair to say you haven't had a publication on medical literature since 2007, correct?
A. No. No. That's not correct, actually. I believe the date was 2011 of my latest peer-reviewed publication.
Q. And what is that publication?
A. That is a reanalysis of the randomized control data from my original trial that was published in 2001, which was a comparison of three different surgical techniques for fixing anterior vaginal prolapse.
Q. Okay. We'll talk about that a little further later on today.
Is it true, ma'am, that your only

source of earned income is working for Mr. Slater?
A. Yes.
Q. Now, Doctor, we're here to talk today about prolapse. And I believe you indicated earlier that there's several different types of native tissue type repairs; is that correct?
A. Suture procedures, yes.
Q. And the various kind of suture procedures that are used, does that depend on the location in the body where the prolapse has occurred?
A. Yes.
Q. So for a cystocele, what are the options? And that's the bladder prolapse, right?
A. Yes.
So a cystocele representing prolapse of the anterior vagina, with the bladder behind it, can be treated surgically by an anterior colporrhaphy, sometimes called an anterior repair. And another alternative would be a paravaginal repair, also done through the vagina. And another alternative would be what's called a site-specific anterior repair.
Q. And those are the three types of native tissue for repairing bladder prolapse?
A. Yes.

Q. Other than those three types of surgical procedures, before Prolift became on the market, were there other repairs for a bladder prolapse?
A. Yes.
Q. And what was that?
A. A surgeon could decide to use a different product. There are a number of kinds of products. We touched on this just briefly yesterday. A biologic, so that could be cadaveric tissue, you know, taken from a cadaver and processed; or what's called a xenograft, which is tissue that's been harvested from an animal, sometimes a pig or a sheep, and processed; or a synthetic mesh, manmade mesh. The surgeon could choose one that's fully absorbable, partially absorbable, or fully permanent.
Q. Okay. So those grafts that you just mentioned plus the three types of surgery is what was available as surgical options prior to Prolift, correct?
A. Yes.
Q. Now, with respect to the three surgical options, do you agree, Doctor, that there were different techniques that individual surgeons would use to perform those surgeries?

A. Yes.
Q. And would you agree that often the outcomes of those surgeries depended on the type of technique that was used by the individual doctor?
A. It could be, yes.
Q. Now, these repairs, they involved the use of sutures, correct?
A. Yes.
Q. And the sutures were used to bring the tissue back in together and sewed it up, basically?
A. Basically, yes.
Q. And they did that to repair tissue that had already been weakened, correct?
A. Yeah. To answer that with a yes or no is not -- it would be incomplete.
Q. You can't answer that with a yes or a no?
A. In -- basically. I'll accept that.
Q. Basically that's true, right?
A. (Witness nodding.)
THE COURT: If you want her to answer completely, it's going to have to be a yes-or-no question.
Do you want her to answer or do you want to move on?
MS. ROBINSON: I'm ready to move on.

THE COURT: Okay. That's fine.
BY MS. ROBINSON:
Q. So the tissues that we have just discussed that have been weakened, they were weakened by things like childbirth, correct?
A. Yes, that's possible.
Q. Age?
A. Yes.
Q. Menopause or lack of estrogen?
A. Possibly.
Q. Why do you hesitate on that one?
A. Age and menopause are inextricably linked. Very difficult to tease that apart in research.
Q. Do you agree that these tissues, there's factors that can aggravate the weakened tissues to extend the weakness, to make it progress?
A. Possibly.
Q. And do you agree that that would include things like heavy lifting or activities that would strain the abdominal walls?
A. Possibly. And that's an anecdote -- anecdotal information that we as surgeons have carried for decades. Recent literature actually does not bear that out.
Q. So one of the problems of these native tissue

repairs was the high recurrence rate; is that correct?
A. The recurrence rate -- well, yes, I'll just say yes.
Q. And when we say high recurrence rate, could you tell the members of the jury what you mean by recurrence rate?
A. So recurrence, like we talked a little bit about before, is when the prolapse comes back. And in a perfect world, that would never happen. But since we're not in a perfect world, that does happen to a certain degree.
Q. When you say it comes back, are we generally speaking about it coming back in the compartment that was treated?
A. Not necessarily.
Q. So the word "recurrence" could be used for multiple things, for multiple -- I'm sorry. Strike that. Let me reask the question.
The term "recurrence," can it be referred to failure in both the compartment that's treated as well as a compartment of the woman's body, the organs that haven't been treated?
A. Yes.
Q. So in scientific literature, do you sometimes

see recurrence rates reflected for the treated compartment?
A. Yes.
Q. And then you also sometimes see them referencing a recurrence in an untreated compartment; is that correct?
A. Yes.
Q. Now, which one of those do you subscribe is the best way to analyze the data?
A. The best way to represent outcomes of prolapse surgery are the outcomes of most importance to women. And I think we mentioned this a little bit earlier, that prolapse comes and it may be fixed by surgery and may come back.
Women don't ordinarily distinguish between the anterior vagina, the apical vagina, the posterior vagina. Those are distinctions that doctors make. Prolapse is prolapse for a woman.
So the outcome of greatest importance to women being the existence of prolapse. That would be one of the more important outcomes in research.
Q. Do you agree, Doctor, that in the year 2000, the anatomic failure rate for anterior colporrhaphy was approximately 40 percent?

A. Yes.
Q. And, in fact, you wrote about that; is that correct?
A. Yes.
Q. And the 2011 [sic] study that you just indicated that you had reanalyzed in 2011, you first published it around the year 2000; is that correct?
A. I'm sorry. I may not be understanding your question. Are you asking the publication date of the original randomized trial?
Q. Yes.
A. Yes. That was in 2001.
(Handing document to the witness.)
(Pause.)
MS. ROBINSON: Sorry about the delay, Your Honor.
BY MS. ROBINSON:
Q. So, ma'am, in 2001 you published a study called Anterior Colporrhaphy, a Randomized Trial of Three Surgical Techniques; is that correct?
A. Yes.
Q. And in that study did you enroll about 114 patients?
A. Yes.
Q. When you analyzed the data, is it correct,

ma'am, that only 109 patients were available to reanalyze the data?
A. I'm sorry, I don't understand your question.
Q. When you analyzed the data from these patients, is it correct that only 109 patients returned for follow-up?
A. No.
Q. Is it correct that only 109 patients returned for follow-up approximately 23.3 months after the surgery when you reported the data?
A. I'm sorry. We may be having a miscommunication. Are you referring to the reanalysis of the original 2001 trial?
Q. I'm referring to the analysis of this trial. And you're right, maybe I misspoke.
You originally enrolled 114 patients, right?
A. Yes.
Q. And for some reason only 109 patients underwent surgery?
A. Yes.
Q. And of those 109 patients, then you only had 83 patients that returned for follow-up that was reported on in your study; is that also correct?
A. Yes.

Q. So that's about 24 percent of your patients that were lost to follow-up, correct?
A. That is correct.
Q. Now, when I heard you testify earlier today, you told this jury that if patients didn't return for follow-up, that means they had a bad outcome; is that right?
A. I'm sorry?
Q. Did you tell this jury today that when patients were lost to follow-up for studies, that was a good indication that they had had a bad outcome?
A. No, I don't believe I testified to that.
Q. What did you tell the jury today about the loss to follow-up, if patients were lost to follow-up and not available to be evaluated?
A. What we know in the literature related specifically to mesh kits is that when women experience complications, they may not return to the implanting surgeon and they may instead seek care at another institution.
Q. So this is a phenomenon that's reserved for mesh kits; is that what your testimony is, ma'am?
A. My testimony is that the literature, the recent literature describing complications in women after receiving a mesh kit is that a high proportion of

them do not return to the original surgeon. That's my testimony.
Q. And have you taken that testimony one step further to say that that indicates that these individuals did not have a good outcome? Is that your testimony?
A. No.
Q. That's not your testimony, right?
A. (Shaking head.)
THE COURT: Right. That's what she just said.
Next question.
BY MS. ROBINSON:
Q. In your study, the 24 percent of the patients that weren't able to be evaluated, how did you consider their outcomes?
A. (Pause.)
Okay. They were simply treated as missing data.
Q. Which means you didn't know what their particular outcomes were; is that correct?
A. That's right.
Q. So with respect to the patients that did have data, is it correct that you found failure rates that ranged from 54 to 70 percent?

A. Yes, that's right.
Q. So 54 to 70 percent of the women who underwent your study had failure rates within two years of the surgery; is that correct?
A. Yes, that's right.
Q. And you calculated the failure rates based on an anatomical cure; is that also correct?
A. Yes.
Q. And you calculated any failures for anyone who had a Stage II or greater after surgery; is that correct?
A. Yes, that's right.
Q. Is it also correct that you only analyzed that with respect to the treated compartment, that being the anterior compartment?
A. (No response.)
Q. If you want to look on Page 2 in the right-hand column down in the middle of it where it says "cure was defined."
A. Yes.
Q. So if I understand this study correctly, three different types of surgery were used to correct a woman's prolapsed bladder, correct?
A. Anterior vaginal prolapse, yes.
Q. You performed the surgeries; and based on

failures in the treated compartment, that being the compartment, the bladder, correct?
A. Yes.
Q. Based on that, you had lost -- you had failure rates of 54 to 70 percent, correct?
A. Yes.
Q. You also noticed -- you noted in the study that this was the first randomized control trial that had assessed anterior colporrhaphy surgeries; is that correct?
A. Yes, that's right.
Q. Now, anterior colporrhaphies had been around for hundreds of years, right?
A. Yes.
Q. And this is the first time that it had been assessed in a randomized control trial for the treatment of prolapse?
A. Yes, that's right.
Q. So you had been practicing medicine for about 13 years before this anterior colporrhaphy had ever been studied through a randomized control trial, correct?
A. Roughly, yes.
Q. And you had been performing that surgery yourself, right?

A. Yes.
Q. And it was not supported with data that would be of a Level I type data, correct?
A. That's right.
Q. And that's the highest data -- you as a trained statistician know that that's the highest kind of data that you can have to assess a person's outcome; is that correct?
A. I wouldn't word it like that. I would say it's the trial design that allows you to compare groups and their outcomes and actually assign a cause and effect to the outcomes.
Q. And moving on to 2004 --
THE COURT: If you're moving off this article, it's time to break for lunch.
MS. ROBINSON: Yes, Your Honor. Thank you.
THE COURT: Okay. Ladies and gentlemen of the jury, we're going to break for lunch at this time. I'll ask you to return at ten minutes to 2:00. Between now and when you return, keep an open mind and don't discuss the case with anyone.
Charles.
COURT CRIER: Please remain seated

until the jury has left the courtroom.
Jurors, follow me. Turn your clipboards over.
- - -
(Whereupon the jury exited the courtroom at 12:23 p.m.)
- - -
THE COURT: Counsel, I understand that we have an objection to the deposition of Aaron Kirkemo hanging. Is there anything else that's hanging?
MR. ISMAIL: Your Honor, the designation of Dr. Hinoul relates to the very same e-mail, so...
THE COURT: Okay. Do we have that deposition that I can look at? Or bring it -- after lunch give me that and let me know what the problem is.
Is there anything else that's hanging?
(No response.)
THE COURT: Is there anything else we need to deal with or can productively deal with at this time?
(No response.)

THE COURT: Then we stand in recess until ten minutes to 2:00.
MR. ISMAIL: Thank you, Your Honor.

(Morning Session concluded.)
- - -
(Luncheon recess was taken.)
- - -
(Whereupon the Afternoon Session was reported and transcribed by Judith Ann Romano, CRR, Official Court Reporter.)
- - -

CERTIFICATION

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the trial of the above cause, and that this copy is a correct transcript of the same.

I further certify that I am not a relative or employee of any attorney or counsel employed in this case.

_____

John J. Kurz, RMR, CRR
Registered Merit Reporter
Certified Realtime Reporter
Official Court Reporter -
Notary Public

(The foregoing Certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

D

Q

R

S

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION :

PATRICIA HAMMONS, : MAY TERM, 2013
Plaintiff:

v. :

ETHICON, INC., et al., :
Defendants : NO. 3913

- - -

Tuesday, December 8, 2015

- - -

COURTROOM 246
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J.,
and a Jury
- - -

JURY TRIAL VOLUME VI

AFTERNOON SESSION

REPORTED BY:
JUDITH ANN ROMANO, CM, CRR
CERTIFIED MERIT REPORTER
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

A P P E A R A N C E S:

KLINE & SPECTER, A Professional Corporation
BY: SHANIN SPECTER, ESQUIRE
BY: KILA B. BALDWIN, J.D., ESQUIRE
1525 Locust Street
The Nineteenth Floor
Philadelphia, Pennsylvania 19102
T: 215-772-1000 F: 215-735-0937
E-mail: shanin.specter@klinespecter.com
kila.baldwin@klinespecter.com
Counsel for Plaintiff Hammons

MAZIE, SLATER, KATZ & FREEMAN
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
T: 973-228-0454 F: 973-228-0303
E-mail: aslater@mskf.net
Counsel for Plaintiff Hammons

DRINKER BIDDLE & REATH, LLP
BY: MOLLY E. FLYNN, ESQUIRE
One Logan Square, Suite 2000
Philadelphia, Pennsylvania 19103-6996
T: 215-988-2836 F: 215-988-2757
E-mail: molly.flynn@dbr.com
Counsel for Defendants Ethicon and Johnson and Johnson

TUCKER ELLIS, LLP
BY: MATTHEW P. MORIARTY, ESQUIRE
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113-7213
T: 216-696-2276 F: 216-592-5009
E-mail: matthew.moriarty@tuckerellis.com
Counsel for Defendants Ethicon and Johnson and Johnson

A P P E A R A N C E S: (Continued)

GOLDMAN, ISMAIL, TOMASELLI, BRENNAN & BAUM, LLP
BY: TAREK ISMAIL, ESQUIRE
(admitted pro hac vice)
564 West Randolph Street, Suite 400
Chicago, Illinois 60661
T: 312-681-6000 F: 312-881-5190
E-mail: tismail@goldmanismail.com
Counsel for Defendants Ethicon and Johnson and Johnson

THOMAS COMBS & SPANN, PLLC
BY: SUSAN M. ROBINSON, ESQUIRE
(admitted pro hac vice)
300 Summers Street, Suite 1380
Charlestown, WV 25338
T: 304-414-1800 F: 304-414-1801
Counsel for Defendants Ethicon and Johnson and Johnson

- I N D E X -

E X H I B I T S

(Hearing is reconvened at 1:48 p.m.)

(ANNE MARGARET WEBER, MD, having been previously sworn, resumes the witness stand.)

THE COURT: Is this another deposition?

MS. ISMAIL: Your Honor, that is the Dr. Hinoul deposition I mentioned before lunch, just the part I marked is the exchange regarding the E-mail that was in the Kirkemo deposition.

THE COURT: Same E-mail?

MS. ISMAIL: Same E-mail, same issue.

THE COURT: So it's the same objection, really?

MS. ISMAIL: Yes, Your Honor.

THE COURT: Great, thank you.

MS. ISMAIL: And I understand it's not ripe for today.

THE COURT: Whenever people want me to decide it, we will talk about it.

MS. ISMAIL: Great, thank you.

THE COURT: But I will read this to see if it's the same.

MS. ISMAIL: Thank you.

THE COURT: So I understand there is a

juror or two in the restroom and as soon as they are ready -- they are coming in? They are coming in.

(The jury enters the courtroom at 1:58 p.m.)

THE COURT: Good afternoon, ladies and gentlemen.

JURY: Good afternoon.

THE COURT: You may proceed.

MS. ROBINSON: Thank you, Your Honor.

- - -

CROSS-EXAMINATION (Continuing)

- - -

BY MS. ROBINSON:

Q Doctor, we had just been discussing some of the high recurrence rates associated with the tissue repairs for bladder prolapse, correct?

A Yes.

Q You continued to follow women who were undergoing surgery for bladder repair by native tissue; is that correct?

A In this trial? Is that what you mean?

Q No, you continued even after the last trial that we were talking about, where you did the study

with the three arms?

A Yes.

Q You continued to study it even further, right?

A I am sorry, I don't understand your question. Do you mean did we continue to follow that group of women?

Q No, no, the issue.

A Oh, just the issue itself. Yes.

Q Yes, the issue of women undergoing surgery for bladder prolapse using native tissue repair, you continued to study that problem; is that correct?

A Yes.

Q And you continued to find that in some of your studies that as much as 58 percent of women would have recurrence within one year; is that correct?

A Not restricted to anterior vaginal prolapse, but, yes, correct.

Q And that would be a study you reported on in 2004; is that correct?

A Yes.

Q Do you agree with what you stated back then, that, "Recurrent poly-organ prolapse after surgical correction is one of the most vexing problems in reconstructive pelvic surgery"?

A Yes.

Q You continue to agree with that?

A Yes.

Q Now as a result of these high recurrence rates that doctors were seeing, did that lead doctors to begin looking at other options for more durable repairs?

A Yes.

Q And in fact, in the late 1990s, 2000, maybe even earlier than that, they started using synthetic mesh in pelvic organ prolapse repair; is that correct?

A Yes.

Q And they were doing the abdominal sacrocolpopexy, or the ASC that I probably should just call it, surgery for that; is that correct?

A Yes. Actually, I mean ASC preceded the use of synthetic mesh through the vagina by a good number of years, but, yes.

Q And ASC, though, repair started using mesh, correct?

A Yes.

Q And the reason for that was to reinforce that native tissue to help preclude recurrence, correct?

A The need for the use of --
Q Is that a yes or no?
A No.
Q The ASC surgery is done for an apical repair, correct?
A Yes.
Q And what kind of repair is that?
A An apical repair, just to make sure I understand, are you asking me to describe the ASC or the indications for the ASC?
Q The apical. What are you trying to repair with the ASC?
A Okay, thank you. The abdominal sacrocolpopexy is used to support the apex or the top of the vagina in a woman who has her uterus and cervix, which can be preserved at that time, or in a woman who has had a previous hysterectomy and prolapse has affected the top of the vagina so it begins to fall down, if you will, inside the vagina at an earlier stage and can actually protrude outside the vagina at a later stage.
Q And in order to perform that surgery, a woman has to be put under, correct?
A (No response.)

Q Anesthesia?
A Anesthesia is required, that's right.
Q She is on an operating table and a surgeon will cut an incision in her stomach, correct?
A That's one method of performing it, yes.
Q So with the abdominal sacrocolpopexy, not using laparoscopic, we are not talking about laparoscopic, but with that procedure, it is a surgical incision, correct?
A Yes.
Q The surgeon then goes down in through all of the muscles and so forth in the abdomen to get to the area that he needs to be in to repair and support the vagina, correct?
A Yes. The muscles aren't cut, they are simply separated.
Q There are some women that, because of the risk of that type of surgery, can't undergo that surgery; is that correct?
A Yes.
Q This might be older women?
A Rarely. Yes.
Q Women that have chronic problems that would make it difficult for them to undergo anesthesia?

A Again, rarely. Yes.
Q Now the doctors then began using mesh in the vaginal area, correct?
A Yes.
Q And long before doctors started using mesh in the vaginal area, vaginal surgeries were fairly predominant, correct?
A I am sorry, I don't understand your question.
Q So doctors, before they started using mesh for repairs through the vagina for pelvic organ prolapse, those doctors were already familiar with operating in the vaginal area, correct?
A Yes.
Q They were performing vaginal hysterectomies, right?
A Yes.
Q And other procedures such as that that would -- the route of injury would be through the vagina, correct?
A Yes.
Q And one of the methods that they started or one of the conditions that they started using mesh to help cure was stress urinary incontinence, correct?

A Yes.
Q And many manufacturers began making mesh for that treatment of that condition, correct?
A Yes.
Q And this was before mesh became available, synthetic mesh became available for pelvic organ prolapse. Is that also correct?
A Yes.
Q Now, you talked a little bit yesterday about the material Gynemesh PS; is that right?
A Yes.
Q Isn't it a fact that you have actually used synthetic mesh for the treatment of stress urinary incontinence?
A Yes.
Q And isn't it correct that when you have written about options for surgery to treat stress urinary incontinence, you have written favorably about the use of mesh to treat stress urinary incontinence?
A If there is a specific article that you are referring to, I would like to see it.
MS. ROBINSON: May I approach, Your Honor?

THE COURT: Charles will be happy to pass up anything you'd like.

MS. ROBINSON: I do, and I would note it for the record.

So for the record, Your Honor, this is Defense 31554.1. And I would also move as an exhibit the -- or just mark the last exhibit that I entered, and we will make the record clear on that.

THE COURT: How are we marking it?

MS. ROBINSON: It's marked and --

THE COURT: Okay, how is it marked then?

MS. ROBINSON: It is Defense 31576.1. Thank you.

THE COURT: Have you had a chance to look at this exhibit?

THE WITNESS: I am looking at it just now.

THE COURT: Let's hear a question, maybe that will help you. Ask a question, and then you look at it if you need to.

Q Does that publication refresh your memory about a writing that you did on sling options for

stress urinary incontinence patients?

A Yes. I was a co-author on this publication.

Q And in that article do you discuss that, "The evolution of SUI surgeries have shifted so far toward mid-urethral slings that Burch colposuspension and the pure vaginal sling are rarely performed or taught in Obstetrics and Gynecology." Is that correct?

A Yes, I did write that.

Q When you are talking about the slings that were used in that stress urinary incontinence surgery, you were talking about polypropylene mesh; is that correct?

A Yes.

Q And you were talking about slings such as Ethicon's TPT; is that correct?

A Yes.

Q And when you were doing that do you recall referring to them as "lightweight," large-pore mesh?

A Yes.

Q Would you agree with me that the Gynemesh PS, the mesh that is used in Prolift, has larger pores than Ethicon's TVT?

A No.

Q You would not?

A No.

Q Do you agree with me that it's slightly lighter weight?

A Yes.

Q Do you agree with me that the pore size is approximately the same?

A No.

Q So you discussed yesterday the Prolift plus M. Do you recall talking with Plaintiff's counsel about that?

A (No response.)

Q Generally, do you recall discussing Prolift plus M yesterday?

A Honestly, I don't, but undoubtedly I did if you are referring to it.

Q Do you recall talking about Ultrapro?

A Yes.

Q Ultrapro mesh. And Ultrapro mesh is the mesh that is used for the product Prolift plus M?

A Yes.

Q And that mesh is made of polypropylene with an absorbable type of material; is that correct?

A Yes.

Q And that product is also used for pelvic organ prolapse; is that correct?

A Yes.

Q And you know that it was considered as a potential use for Prolift, correct?

A Yes.

Q And at the time, it had not been fully evaluated, when Ethicon put Prolift on the market; is that correct?

A Yes.

Q Now I just want the jury to know, Ma'am, do you think it's okay to use any kind of synthetic mesh for the repair of pelvic organ prolapse through the vagina?

A No.

Q Now you are interested in the area of the literature and the material surrounding pelvic organ prolapse and that condition; is that correct?

A Yes.

Q And you keep up with it even today, correct?

A Yes.

Q And you have read literature currently about Prolift plus M; is that correct?

A Yes.

Q Or Ultrapro?
A **Yes.**
Q And do you agree with me that some of that literature would indicate that up to 14.8 percent of women undergoing the use of pelvic organ repair with Ultrapro has a risk of mesh erosions?
A **I am sorry, could you repeat that?**
Q Yes, I will try.
THE COURT: Does the literature show that there is a risk of mesh erosion up to 14 percent or a little more than that?
THE WITNESS: With the Prolift plus M, yes.
Q And do you also agree with me that there is literature that shows that with Prolift plus M there is up to 9 percent risk of dyspareunia or pain with sex?
A **If you are referring to a specific article, I would like to see it.**
THE COURT: Well, do you know, without referring to an article?
THE WITNESS: I do not know that figure, the 9 percent.
THE COURT: Okay, next question.

Q How high of a figure do you think the dyspareunia rates have shown for Ultrapro?
A **I can't pull that off the top of my head.**
THE COURT: Why don't we move on while you are trying to find that article.
Q Doctor, if you will just take a review of Defense 30989.1. And I want you to look at -- if you look on the right-hand column there, to make it a little bit easier for you, where it talks about the de novo dyspareunia rates?
A **Yes.**
Q And does this refresh your memory that there have been presentations presented that would show dyspareunia rates up to 9 percent involving Ultrapro?
A **In this one abstract, yes.**
Q Now you have testified here today that quality of life is one of the important factors in determining success of a prolapse surgical procedure; is that correct?
A **Yes.**
Q Do you have an opinion as to what stage of prolapse would have to exist in order for a woman to have a negative impact on her quality of life?

A **That's a very good question, and something that has been studied, without a definitive answer.**
By the beginning of early Stage III, which is in POP U system where the vagina is protruding outside of the hymen by more than one centimeter, one centimeter is like half an inch, roughly, women may become aware of that. Now, of course, awareness is not necessarily a negative impact on their quality of life. And there isn't a linear relationship, there is not a straight line between the degree of prolapse and women's awareness or being bothered by, whether or not they are aware of the prolapse.
Q So women that have a Stage II prolapse, for example, would you say that most of them are not symptomatic with prolapse?
A **No, I wouldn't say most.**
Q Do you agree that most women that have Stage II prolapse can still have a good quality of life?
A **You are speaking, I assume, specifically health-related quality of life specific to her prolapse?**
Q Correct.
A **Again, I wouldn't say most, but certainly that**

occurs.
Q Recently when you have assessed and studied pelvic organ prolapse, where does the staging fall into your determination of how you assess here?
A **The most recent recommendations which I agree with involve prolapse above the hymen, and a woman who is not symptomatic of bulge or bulge symptoms or other symptoms that she had had in association with the prolapse.**
Q And are Stage II women, a woman who has been staged at Stage II, is that above the hymen?
A **Stage II is defined as women where the prolapse exists one centimeter above the hymen, zero, which is at the hymen, and one centimeter beyond the hymen. So it's that little 2-centimeter space that is included in the definition of Stage II prolapse.**
Q I'd like to show you the Clinical Study Report, I believe, and it's DX257534. Actually, that may be the statistical analysis. Ma'am, do you recognize that?
A **Yes, I do.**
Q Now you have reviewed a lot of Ethicon's records related to the TVM French study report; is

that correct?

A Yes.

Q And do you recognize this as a statistical analysis plan for, I believe this is the five-year data?

A Yes.

Q And how does a statistical analysis plan fit into a clinical trial?

A The statistical analysis plan is the part of the protocol that is ordinarily developed before any of the data are collected or analyzed, to set out how in fact the data are going to be analyzed.

Q I want to refer you to page 11 of that document.

A Yes.

Q Do you recognize this as sample data collection form for follow-up observation?

A Yes.

Q And does this document help the physician when they have a patient, or lady, I mean these are real people that are having these studies, right?

A Yes, they are.

Q And does this document help the physician assess the women when they follow-up for care?

A Yes.

Q And you would agree with me in this case that Ethicon was collecting information to evaluate the patient at six, 12 months, three years, and five years, correct?

A Yes.

Q And that they were assessing the impact of the prolapse on their sexual activity, correct?

A Yes.

Q They were impacting the prolapse -- or assessing the impact of prolapse on vaginal pain?

A No, not -- that's not what it says.

Q If you look under the vaginal pain section, do you see where they were conducting examinations to determine if an examination provoked dyspareunia, for example?

A I do. If I understood your previous question correctly, I thought you had stated directly related to the impact of prolapse.

Q This is, and I maybe misspoke and thank you for clarifying that, this is the impact of the treatment, on whether it has caused these problems for the women, in follow-up, correct?

A Yes, that's the intention of this data gathering.

Q So Ethicon was studying whether their product was going to cause women to have pain with sex, correct?

A That was on this data form. I have not seen this on previous data forms that I reviewed.

MS. ROBINSON: Your Honor, move to strike.

THE COURT: Was Ethicon studying or not, or you don't know?

THE WITNESS: No, not in the case forms that I reviewed.

THE COURT: Okay, next question.

BY MS. ROBINSON:

Q If you look at page 12, you see this is an assessment form for postoperative quality of life; is that correct?

A Yes.

Q And this also is for the TVM French study, which was documented as 2003-016; is that correct?

A Yes.

Q And Ethicon by these forms was collecting information on what impact their product Prolift had on the quality of life of women; is that correct?

A Yes.

Q And they were assessing such things as whether some of the symptoms that they have interferes with their sexual relationships, correct?

A Yes.

Q They were assessing whether Prolift would affect them so it would interfere with them pursuing new relationships with people, correct?

A The symptoms the woman was experiencing at that time would prevent them from pursuing new relationships, yes.

Q And also other things, such as how their bowel habits were at the time after having their product, correct?

A Yes.

Q And those are all important things that you want to know about a product that's out there to treat pelvic organ prolapse, correct?

A Yes.

Q I want to go to slide three.

Now do you recognize this as the list of women who had failures at 12 months as tallied by Ethicon in its TVM French study?

A Yes.

Q When you look at this table, you see that each of the women, with the exception of one, were at Stage II, correct?

A Yes.

Q And even though they were at Stage II, they were considered failures; is that correct?

A As defined in the protocol, yes.

Q And only one was a Stage III?

A That's correct.

Q Now you also know that in the study, that Ethicon enrolled women who were at Stage III and IV, correct?

A That was the intention, yes.

Q I want to take a minute and just walk you through one of these patients. Let's look at what information Ethicon collected on Patient 6003. Can you go to DX25019.146.

(Pause.)

Q So what we have here is Patient 6003, and she was deemed a failure at study, correct? The kind of information Ethicon was collecting, we see at baseline --

THE COURT: Whoa, whoa, did you want an answer to that question? Did you answer?

THE WITNESS: No, I didn't.

THE COURT: I didn't think you had. Do you want an answer to that question?

(No response.)

THE COURT: Okay, it's not answered. Next question.

MS. ROBINSON: Your Honor, I am going to mark for the witness' benefit D25019.114.

Q Ma'am, if you can look at....(Pause.)

Ma'am, if you look at page 119 of that document, and that should give you Patient 3006?

A Yes.

Q And you see on there that she has a baseline of POP Q score; is that correct?

A Yes.

Q And baseline just means her condition prior to surgery, correct?

A Yes.

Q And what stage was she before surgery?

A Stage IV.

Q And she had a combined-type surgery, so she had more than just one prolapsed organ, correct?

A I believe what "combined" refers to is receiving the total anterior and posterior TVM

implant.

Q So she was in an overall stage of IV. Do you see that in the anterior she was at a Stage III, in the posterior she was a Stage III, and a Stage IV in the apical; is that correct?

A Yes.

Q Now after she received treatment, she follows up at six months, and even at six months, at that point she is a Stage II and considered a failure, correct?

A Yes.

Q But if you look across the lines there, does it appear that she is only a failure in one compartment at that point?

A (No response.)

Q You see she is a Stage II in the bladder prolapse section and Stage 0 in the posterior and apical?

A Yes, that is correct. At six months and one year and at three years she is a Stage I in the apical compartment, and also at five years, while she remains a Stage II in the anterior compartment.

Q The one I am looking at has zeros, but notwithstanding that, her prolapse overall doesn't

go down from Stage II throughout the whole entire five-year period that she is studied, correct?

A Yes.

Q Now Ethicon studied her quality of life; is that correct?

A Yes.

Q And can we go to slide four now.

I want to approach and hand you D250191.36. Now let's look at Patient 6003's Quality of Life assessment. Now Ethicon assessed these from one to ten, correct?

A I am sorry, can you direct me to what page you are on?

Q Page 146. And if you look at Patient 6003, do you see she has Quality of Life scores for one-year and five-year data, correct?

A I am sorry, which column are you looking at? Is that the first column? Prolapse affecting life?

Q Yes.

A So that represents a visual analogue scale that's not validated.

Q Do you agree that this is a Quality of Life Assessment form?

A Yes, again, just the caveats that we already

mentioned.

Q Do you agree that this is the table that tabulates the information that the woman has provided on the Quality of Life Assessment form that we showed the jury just a few minutes ago?

A Some of it, yes.

Q And as the patient answered those questions and was assessed, at one year she was assessed at having a quality of life of 9.91, correct?

A Yes.

Q And at five years, she remained to have a quality of life value of 8.47, correct?

A That is -- those are the numbers, yes.

Q And that is on a scale of one to ten?

A That is correct.

Q Ma'am, I am handing you Defense Exhibit 25019.80.

A I am sorry, could you repeat the number?

Q 25019.

A And were there extra digits?

Q What's the digits in front of you?

A .54.

Q Yes, and can you look at Patient 3006 on that form?

A Can you direct me to a page?

THE COURT: Okay, we are going to take a ten-minute recess at this time. Everyone please remain seated while the jury leaves the courtroom.

(The jury is excused from the courtroom at 2:42 p.m.)

THE COURT: How many more of these documents do you have, Ms. Robinson?

MS. ROBINSON: Two more.

THE COURT: And are there any other documents that you are going to be using with this witness after these two more?

MS. ROBINSON: Yes.

THE COURT: How many other documents?

MS. ROBINSON: Maybe a half dozen. But not like these forms.

THE COURT: You are to give the witness all the documents that you intend to use in your cross examination, and if there are specific lines that you wish the witness to look at, like has happened with the last three packets, you are to highlight those lines.

MS. ROBINSON: I will do that, Your

Honor.

THE COURT: Anything further before we recess?

(A brief recess is taken.)

THE COURT: Court is back in session, please be seated. Do you intend to ask the witness about specific portions of these articles or just generally about the articles?

MS. ROBINSON: I have provided to the Court articles --

THE COURT: I am sorry, do you want the question read back? Read back the question I asked, please.

MS. ROBINSON: Just generally.

THE COURT: Fine. Give those documents to the witness and let her tell us when we are ready, and then bring in the jurors.

(A further recess is taken.)

- - -

(The following transpired at 3:04 p.m.)

THE COURT: Did you get a chance to look at those things?

THE WITNESS: Yes, I did.

THE COURT: I am told they are going to

ask specific questions about lines on those charts and general questions about those articles. Are you generally familiar with what those articles are?

THE WITNESS: Yes.

THE COURT: Okay. Give them to counsel.

(The jury enters the room at 3:05 p.m.)

THE COURT: Since you just received them, counsel, do you need some time to look at them?

MR. SLATER: No, we are fine, Judge.

THE COURT: Next question.

BY MS. ROBINSON:

Q Ma'am, in front of you is Document 25019.60 is the page number.

A Yes.

Q Now I will pull it up here. This is a chart that is analyzing sexual impact; is that correct?

A That's one of the issues. I am just a little worried that the jury may not be seeing this.

THE COURT: Well, then that's up to counsel to worry about. Next question.

THE WITNESS: Okay.

Q So this is a dataset. You are used to analyzing these, correct?
A Yes.
Q And I want you to look at Patient 3006.
A Yes.
Q And cross through there, and it identifies that this patient has had no problem with sexual activity; is that correct?
A As baseline, yes.
Q And throughout the six-month, one-year, through three and five years, still remains?
A It says, "No sex other cause".
Q So at this point she may not be engaging in sexual activity, correct?
A That's the meaning. She is not. Not that she may not.
Q And the causation is not -- that indicates it's not related to the Prolift device, correct?
A I don't believe that's one of the choices, as to whether it's related to the Prolift. She went from a baseline of having no limit to her sexual activity to being not sexually active after surgery.
Q And then when it indicates "other cause", based on your review of these forms, did you

understand that that meant that it was a cause unrelated to the device?
A That was not one of the choices.
THE COURT: Is that your understanding? Read back the question.
(Pending question is read by the court reporter.)
A No.
Q If you look at the top, do you see that Ethicon is also collecting data on vaginal retraction?
A Yes.
Q And you see that for this lady, each of the time points for her follow-up she had no vaginal retraction, correct?
A Yes.
Q Now I want to show you -- you can set that aside. I want to go back and look at slide number three, which was all of the failures that Ethicon listed for the TVM at 12 months, and I want to take a look at the Quality of Life assessments for them, and that is going to be slide number five.
So after one year, where they have measurements, most of these women were in at least

the seven to ten range. Do you see that?
THE COURT: Do you know what this slide is showing?
THE WITNESS: Yes.
THE COURT: Do you see whatever it was that you were asked if you saw? Ask the question again, please. I interrupted.
Q The patient numbers reflect the patients that were deemed failures as a result of the study, correct?
A That Ethicon counted, yes.
Q And they counted the recurrences, and these women had a recurrence, correct?
A Yes.
Q And for each of those women where we have values thereafter one year, and then again after five years, it reflects their level of satisfaction, indicating that they were pleased with the operation on a level of one to ten, with ten being the highest; is that correct?
A Except for the six women for whom there is no information, which is concerning to me, yes.
Q Now you are referring to the six women that you have had added to the failures, correct?

A No, I am referring to the six women who do not have a score on your slide.
Q Okay, so the six women who don't have a score, that's just values that weren't available at the one-year time period, correct?
A No, I believe that means they didn't fill out that questionnaire.
Q Does it also indicate to you that after five years all but one also filled out the questionnaire?
A Yes. Also, the numbers are substantially lower.
Q So you agree with me that the TVM group published their results of their one, three, and five-year data, correct?
A No.
Q You do not agree that Ethicon published their one, three, and five-year data?
A No, I don't believe so.
Q Do you recall an article by Jacquetin?
A Could you be more specific?
Q Do you recall the TVM article by Jacquetin that was publishing in the five-year data, correct?
A Yes.
Q And is your problem with my question the fact

that you don't believe they published for each of the years that I mentioned?

A Yes.

Q Okay. So you know they published the five-year results?

A The French TVM group, yes.

Q And that's what I am talking about.

A Yes.

Q So the data that we have been looking at here was published by the TVM group after five years, correct?

A Yes.

Q Now you reanalyzed that data, and that's what you presented to the jury here today.

THE COURT: That's a statement. Any further questions?

Q Did you reanalyze the recurrence rates for the TVM study?

A Not at five years.

Q Did you reanalyze the rates for three years?

A No, I did not.

Q So what was it that you gave to the jury today when you were talking about the failure rates of the TVM study?

A Perhaps I misspoke. I know for sure that it was the one-year for the French and the U.S., and I may be mistaken but I don't believe that included the three and the five-year results, where I analyzed it to the level of the case report forms.

Q You agree with me that your reanalysis, whatever it was, has never been published, right?

A That's right.

Q It's never been peer reviewed, right?

A That's right.

Q No independent person other than you have reviewed that data; is that correct?

A No, that's not correct.

Q And is that another person that was working for Plaintiff's counsel that helped you with the data?

A No. It was not someone who helped me with the data.

Q Was it somebody that prepared the data and provided it to you?

A No.

Q Who was it?

A It was someone who performed an independent review of the case report forms.

Q Was she paid for by Plaintiff's counsel?

A Yes.

Q And this data that you analyzed, was that part of what you were paid to do, is that right?

A Yes.

Q And all of the millions of pages that you reviewed, and that's what's got you here so that you are being paid a thousand dollars an hour to testify; is that correct?

A Yes.

Q So the Lucente data that you talked about and reanalyzed, that data came from Dr. Lucente and Dr. Murphy, correct?

A Yes.

Q And it was a spreadsheet that was provided to you; is that also correct?

A Yes.

Q You did not, with that data, you did not go back and look at the actual patient information?

A No. That wasn't available to me.

Q So you were not able to take their spreadsheet and compare it with the individual lady's chart in order to determine whether it was correct or not; is that the case?

MR. SLATER: Your Honor, can we approach sidebar with an objection, Your Honor?

THE COURT: Sure.

(The following transpired at sidebar:)

THE COURT: Yes, what's the objection?

MR. SLATER: We were told not to pick up the subpoenas and that's how we got this data. We did everything we could to get the patient level data and couldn't get it through the subpoenas, so it was blocked. So it was not something that would ever possibly be available, it was blocked. So I think it's unfair to ask this witness if it was something she should have looked at if it was legally impossible for us to get it.

THE COURT: If they are asking about why she doesn't have it, you can follow up with questions about why she doesn't have it.

MR. SLATER: Okay, thank you.

THE COURT: But the objection is overruled.

MR. SLATER: Fair enough.

THE COURT: Judy, read back the last

question.

(Pending question is read by the court reporter.)

A Correct, I did not have available to me the patient charts.

Q You did have available to you, though, the depositions of Dr. Murphy and Dr. Lucente where they discuss this data; is that correct?

A Yes.

Q And in review of the information that you learned during those depositions, did you come to an understanding that the information on the spreadsheets may be incomplete?

A The information in the deposition testimony was contradictory. It was difficult to tell what either Dr. Lucente or Dr. Murphy knew about this database and what they could tell the lawyers in their deposition testimony.

Q And they were not able to verify for you that that was a complete set of the data of the women that they had treated; is that correct?

A I don't believe they were able to verify about that, yes.

Q Do you agree with me that data that can't be

verified shouldn't be put out to the medical community?

A That would be a general principle of clinical research. And they did anyway.

Q And you took the spreadsheets that they had and you analyzed it as well, correct?

A Yes, that's correct.

Q And in doing that, you learned that a lot of these women had more than one procedure performed at the same time; is that right?

A Yes.

Q And when you listed the information for the jury as to the particular incidences of adverse events that these women had, you did not attempt to relate that one way or the other to the product; is that correct?

A Yes.

Q You also didn't use a protocol when you reviewed those spreadsheets?

A Well, yes, I did.

Q Was that your own protocol?

A I used the protocol of Dr. Lucente to the extent possible. It was extremely brief, only four pages long, and did not contain the kind of detail

that a normal, rigorous sort of protocol for a scientific study would include.

Q Based on the information available to you, you did not determine how Dr. Lucente and Dr. Murphy were counting failures, did you?

A In the protocol they defined failure as a patient who had a prolapse of Stage II or greater, or a patient who required a reoperation for prolapse.

Q When you reviewed the data what did you consider as a failure?

A Those two factors, also, in the database itself the patient would be declared a failure, different terminology was used, support defect, the fact that she had had a reoperation despite being characterized as a success in the final column.

If I had my summary report of my analysis of that database I could be sure that definition was as complete as it could be. That's the main factors that I remember right now.

Q But your definition was different than the protocol?

A My definition was drawn from the protocol and words in the spreadsheet that unequivocally assigned

a woman to a category of failure.

Q Based on your opinion?

A No, it's not my opinion. If someone writes "support defect" in the spreadsheet, that in medical terminology, in research terminology, that is a failure.

Q Do you have any sense as to whether the study, Murphy and Lucente study was counting failures in treated compartments only?

A I would have to look back at the protocol to be sure. I counted it both ways, to have both numbers accessible.

Q When you assessed Lucente's and Murphy's spreadsheet you counted failures as if it would be in either compartment would count as a failure, right?

A If they declared it was a failure, I counted it as a failure.

Q And when you did your own study back in 2001, you only counted failures when they were in the treated compartment; is that correct?

A That was the endpoint of that randomized trial, yes, one of the endpoints.

Q Now you would agree with me that when you

looked at the TVM data for the exposure rates, that you calculated the exposure rates based on whether the mesh was palpable, correct?

A Yes.

Q And whether it was visible and palpable, correct?

A Yes.

Q And if it was just visible. Is that right?

A Yes.

Q And you counted all of those; is that correct?

A Yes, as defined in the protocol.

Q What does palpable mean?

A Palpable means that the doctor can feel the mesh erosion, the pull, if you will, in the vaginal wall with the examining hand or fingers.

Q Palpable is still under the skin, right?

A No.

Q When you feel something that's palpable, has it come through the skin?

A Yes.

Q A palpable mesh has come through the skin?

A A palpable mesh erosion has come through the skin.

Q And that's your definition?

A Yes.

Q When you were defining erosion before, I think you called it as something that was eating away through the lining and could be seen in the vagina?

A Yes.

Q So how is palpable and visible different?

A Palpable, the reason a doctor may only be able to palpate a mesh erosion and not at the same time be able to see it is depending on the contour of the vagina itself. The normal vagina has folds and rugae, that's the term for those little ups and downs on the vaginal wall. Also, after the mesh implantation there may be vaginal anatomic distortion, so that it's not possible to see clearly into all of the areas of the vagina. So the doctor can palpate it with his finger, but he just can't arrange his instruments, the speculum, the woman may be very uncomfortable during the examination and he doesn't want to make it worse for her, so he may just not be able to actually make it visible at the same time that he is able to palpate.

Q Ma'am, I think that your attorney gave you a Clinical Study Report earlier as an exhibit for the French data, correct? Do you have the Clinical

Study Report in front of you?

THE COURT: Do you have a copy you can pass up?

THE WITNESS: I do have it, Your Honor.

THE COURT: Okay, great.

MS. ROBINSON: It's page 49. It's actually 48 and 49, where it discusses the TVM mesh exposure.

Q On page 49, do you see up at the top, do you have an understanding as to whether the TVM doctors considered a mesh that was palpable to be a mesh exposure?

A I see what you are referring to. That's not generally how it's understood in the medical community.

Q So, ma'am, is it the case that some of the women that you assess as having mesh exposure had palpable exposure rather than, as these doctors have indicated it should be counted where it's either visible or visible and palpable?

A That's possible.

Q So you have a list of women that you have added to the failure, to the mesh exposure group, right, and those women basically have palpable mesh,

correct?

A No.

Q You have in front of you Defense Exhibit 25019?

A Okay.

Q And I would like you to turn to page 11 -- I am sorry, 109 and 110.

A Okay.

Q And I have highlighted for you --

A Yes.

Q Patients Number 7006 and 7010. Were those patients that you added to the failures that Ethicon had?

A I would need to see my list of the mesh exposures.

Q I am going to hand you, just for purposes to see if it refreshes your memory, my copy of your list.

THE COURT: Read the exhibit number for the record, Charles.

THE COURT CRIER: It says Weber 15. Weber 15, Your Honor.

THE COURT: Give it to the witness.

Q Do you recognize that as an exhibit that you

would have seen during your deposition in August of this year?

A Yes.

Q And on the back page does it list the patients that you counted as having mesh exposures?

A Yes.

Q And is Patient 7006 on that list?

A Yes.

Q As well as Patient 7010?

A Yes.

Q And I will refer you back and we will show the jury DX25019, page 109.

Do you see that Patient 7006, at six months and one year only had palpable mesh?

A Yes.

Q And you see that at three years and five years, without treatment, neither one of those patients had any palpable mesh?

A Yes.

Q Now that's a patient that you counted, correct?

A Yes.

Q Now you reanalyzed your own data, didn't you, your own data from your 2001 Study that showed

failure rates in the anterior colporrhaphy repair range from 54 percent to 70 percent, you reanalyzed that data; is that correct?

A Yes.

Q And you did that in 2011?

A The Study was published in 2011, yes.

Q When you published the Study, those rates went way down; is that correct?

A Yes.

Q And you found that many more women had successes from the anterior colporrhaphys than you had originally published, correct?

A Yes. It was a different definition.

Q Now when you published this in 2011, did you disclose that you had been working with Mr. Slater?

A No.

Q You didn't think the medical community needed to know that you were working for an attorney representing women who had complaints having to do with Prolift?

A No.

Q You didn't think that was important?

A That is not a standard in medical publishing.

Q Earlier today you testified about the ACOG

manual? Do you have a copy of it up there?

A The Practice Bulletin?

Q Yes, the Practice Bulletin.

A Yes.

Q And I am going to show you the language that you referred to that was removed from the Practice Bulletin, and that language was whether this was an experimental procedure, correct?

A Yes.

Q When it was republished in September of 2007, do you agree with me that the only words changed or removed from that publication were the ones that are highlighted there?

A Yes.

Q So everything else in that whole entire Practice Bulletin is exactly the same, right?

A Yes.

Q No one changed anything about what you said about Prolift or mesh kits in that Bulletin, correct?

A Except --

Q Except for the "experimental"?

A Right.

Q You had other information in that Bulletin

about the outcomes related to the mesh kits, correct?

A Yes.

Q And nobody took that out, right?

A That's right.

Q You also were asked about a letter that you wrote after this change had happened; is that correct?

A After the publication of the article of Drs. Wall and Brown, yes.

Q And this is what you had to say about that, right?

Do you agree with me that before the change was made in September of 2007, that it underwent the exact same review as it did the first time it was published?

A I think you are mistakenly representing what is on the screen at the moment.

THE COURT: Well, let's start with is that what you want on the screen?

MS. ROBINSON: No, we can take the screen off --

THE COURT: Take the screen down. Do you want the question read back or stated

again.

THE WITNESS: Yes.

(The question is read by the court reporter.)

A That's what ACOG said. That's not what I was told by people who attended that meeting.

THE COURT: So would you agree with counsel or not?

THE WITNESS: No, I don't agree.

Q So let's talk a minute about dyspareunia or pain with sex. Do you agree with me that there are many factors that can cause dyspareunia?

A Yes.

Q Do you agree that eight to 13 percent of middle-age women can have sexual dysfunction?

A If you are referring to a specific document, that may help.

Q If you want to look in front of you.

MS. ROBINSON: I am going to apologize to the Court because I wasn't planning on using this document.

THE COURT: It's okay.

Q I am going to hand you Exhibit D32265. I will ask you to look at that and see if it refreshes your

memory about an article that you wrote back in 2000?

A Yes. Perhaps I misheard the question. But I see what you are referring to, yes.

Q Okay, and my question again is do you agree that there is a high prevalence of sexual dysfunction in middle-aged and elderly women in the community, including dyspareunia, which ranges between eight to 13 percent?

A Yes.

Q Do you agree that there are many factors that can have a woman to have high occurrence of dyspareunia including menopause?

A That's a possibility, yes.

Q Vaginal dryness or atrophy?

A Yes.

Q Symptomatic pelvic organ prolapse?

A Yes.

Q Prior vaginal surgeries?

A Yes.

Q Including a total vaginal hysterectomy?

A Possibly, yes.

Q Anterior colporrhaphy?

A Yes.

Q Posterior colporrhaphy?

A Yes.

Q In fact, would you agree with me that posterior colporrhaphy can have a range of dyspareunia that can equal close to 26 percent?

A Yes.

Q You have also found, have you not, that the normal vaginal length for a woman has been reported to be between seven and 11 centimeters, correct?

A Average. Average may not be exactly the same as normal.

Q So when you are a doctor and you are trying to determine what you consider to be a woman's normal vaginal length, what term do you use, average or normal?

A I mean the words have different meanings. I guess I don't understand your context.

Q Well, I am trying to figure out what the difference is between average and normal as you have just stated?

A Well, that's what I stated in this article, where we were endeavoring to describe vaginal dimensions that would be favorable to achieve at the time of reconstructive vaginal surgery for prolapse. So the average posterior vaginal length has been

reported from seven to 11 centimeters.

Q Now the study you did here in 2000 involved women undergoing repair for a posterior repair, correct?

A That was one of the procedures that was performed, yes.

Q And in your study did you determine that 19 percent of the women after undergoing the surgery had dyspareunia?

A Yes.

Q You stated, in fact, that posterior colporrhaphy is significantly associated with dyspareunia?

A Yes.

Q What does that mean "significantly associated"? Is that a statistical term?

A Yes, I believe so, in that situation. Yes.

Q I want to ask you just a couple of last questions. Is it true that there are more randomized control trials for Gynemesh PS than any other product for pelvic organ prolapse?

A Yes.

Q Is it also true that there are more randomized controlled trials for the Prolift kit than any other

mesh kits out there for pelvic organ prolapse?

A Yes.

MS. ROBINSON: Thank you.

THE COURT: Mr. Slater, is there any redirect?

MR. SLATER: A little bit, Your Honor.

\- - -

REDIRECT EXAMINATION

\- - -

BY MR. SLATER:

Q Doctor Weber, let's go over a couple of quick things. I will try to be brief. We have some other stuff to do.

You testified to the fee that you are charging for today's testimony?

A Yes.

Q When you are not in court what's the hourly rate that you charge?

A $350 an hour.

Q The numbers that you charge to my law firm, did you pull that out of the air, where did you come up with those?

A No. When we first spoke about the possibility of working together, I asked some of my

colleagues -- I hadn't done this kind of work before -- what was considered reasonable and customary.

MS. ROBINSON: Objection.

THE COURT: Overruled.

A And you and I also discussed what was reasonable and customary in your experience, and that is how we settled on that figure.

Q Now the opinions that you put into that letter about what those people on ACOG did in changing your Bulletin and the strong statement you made to the public, did you make those statements and form those opinions before or after you ever spoke to me?

A Before.

Q You were asked about being Board certified in female pelvic reconstructive surgery. Is that a Board certification that existed when you were treating patients?

A No. It only just came this year.

Q You were asked if you had witnessed pelvic surgery. Have you witnessed videos of actual surgeons performing Prolift surgery?

A Yes.

Q Have you seen more than one of those?

A Yes.

Q The article that you published in 2001, that was not just you, you had coauthors, right?

A Yes.

Q Tell the jury about some of your coauthors, who else published that article with you?

A So in 2001, which was the randomized trial of the three different anterior repair techniques, my coauthors were my partners in our practice at the Cleveland Clinic. Mark Walters, who had served as an officer in the professional organizations that we have been talking about, the American Urogynecology Society and so on, and then a couple of my senior partners who had been doing prolapse surgery for decades, and a statistician.

Q Now, the 2011 article, who were your coauthors on that article?

A So that included the original surgeons if they were still at the clinic, a couple -- my senior colleagues had retired by that time.
Dr. Chimelewski, who is the lead author on that article, was a fellow at the Clinic at that time so she was in the advanced training that urogynecologists get. Dr. Matt Barber, who is a

staff member at the Cleveland Clinic, also, he had just recently finished serving as president for the American Urogynecologic Society.

Q So the decision to reevaluate those statistics, was that your decision alone?

A No.

Q The former president of AUGS was also one of the people?

A Yes. It was actually his idea, and then we all worked on the analysis together.

Q Now you were just asked about an article from 2000 about dyspareunia rates with posterior repairs. Do you remember that?

A Yes.

Q Is there a little more information to that, about the prevalence and which patients had that and the types of procedures being done that you could share with the jury please?

A I am sorry?

Q That you could share with the jury, please?

A Oh, yes. So this article about sexual function described women who were undergoing a number of different procedures, because prolapse very rarely occurs in one part of the vagina.

Remember we talked about the compartments and how we artificially separate that out. But that's not really how the body functions, so it's very common for more than one aspect of the vagina to be affected at the same time, and also to have incontinence and possibly some bowel issues. So this was surgery to care for all the women's problems at once, and so they had a combination of procedures to help take care of that, and then we followed them over time and assessed their sexual function.

Q Okay, now, doctor, you were also asked about another article that -- it would be the first article, if you have that PLT -- actually, they gave you the defense exhibit, but it's the 2001 randomized control article?

A Okay, go ahead.

Q You were asked about the recurrence rates. In terms of whether or not anterior colporrhaphy, the suture procedure to treat bladder prolapse, in terms of whether or not that provides relief of symptoms and a good functional result, what did you conclude in that article?

A Yes. The women had a very good functional

result, which means their symptoms improved greatly after the surgery, and they didn't experience new complications or severe problems. In this group of women no one needed a reoperation for prolapse, and there were no reoperations or complications.

Q Now going with that, if a woman has a recurrence and needs to have something done after a suture repair, as opposed to a reoperation due to a mesh-related complication, are we looking at the same thing or something different?

A No, those are two totally different categories.

Q Very simply, why?

A A reoperation for prolapse, after a woman has had a suture procedure, she still has open to her any of the other alternatives. It doesn't preclude her from having any of the other different kinds of operations. If a woman is having a reoperation for a mesh complication, that's a very different and serious matter, that if her complication is so severe as to require surgery, there is a high level of possible morbidity to the nearby organs, and morbidity just means more complications. The bladder is right nearby, it's very common to have an

injury to the bladder because of the way the mesh is embedded in the tissues and the way the bladder wall grows into the mesh, just like on the other side the vaginal wall grows into the mesh, and I am speaking specifically the anterior here but the same thing happens posteriorly. So if the surgeon has to try to remove mesh, then there is a high likelihood of creating damage in the bladder in trying to get the mesh out of the bladder wall.

Q Now you were asked about the person who also reviewed the data from the Gynemesh PS study and the TVM study, remember Ms. Robinson asked you some questions about that person?

A Yes.

Q Just so we understand, who was that person?

A That was Dr. Susan Shot. She is a biomedical statistician, and this is what she does for her livelihood.

Q In fact, on that *Iglesia* article I gave you, the one that talked about the 15 percent stopping point, was she involved with that study?

A Yes, she was the statistician of record and a co-author on the publication.

Q We heard about the IIS study, that studied

Dr. Lucente's data?

A Yes.

Q First of all, pursuant to the agreement between Dr. Lucente and Ethicon, did Ethicon have the ability to obtain and review that data?

A Yes.

Q And you were asked a question about deposition testimony of Dr. Lucente, and I just want to -- if I could just hand this up, please.

Doctor, what I would like to do is draw your attention to specific testimony. You relied on these depositions?

A Yes.

Q You were asked about them on cross examination?

A Yes.

Q If you could turn to page 33, please. You were asked questions about whether you had the complete data?

A Yes.

Q Page 33, line eight, the question of Dr. Lucente, which was in his deposition of June 10, 2014, "The data that was produced for the Prolift database and the TVT secure study that were funded

by Ethicon that are identified in this letter, where we provided all the data in existence with regard to those two studies?"

His Answer: "That's my understanding, yes.

"Q And you confirmed that before it was produced to us?

"A Yes."

Did you rely on that testimony from Dr. Lucente?

A Yes, I did.

Q And if you could turn, please, to Page 111, line 9, question of Dr. Lucente:

"Q To your knowledge, there are no other databases that encompass patients within this Prolift study, otherwise you would have produced it to us, correct?"

And Dr. Lucente said, Yes. Correct?

A Yes.

Q Based on that testimony, do you feel comfortable that you saw all of the data that Dr. Lucente had on that study?

A Yes.

MR. SLATER: No further questions, Your

Honor.

THE COURT: Is there anything further?

MS. ROBINSON: No, Your Honor.

THE COURT: Thank you. Ladies and gentlemen, we are going to take a brief recess and see what's next, and then after the jury leaves the courtroom you can step down. Thank you.

(The jury is excused.)

- - -

(The witness is excused.)

- - -

THE COURT: Who is your next witness?

MR. SPECTER: Your Honor, we have two brief videos to show, they are 20 minutes in length total, and then we have Dr. Zipper.

THE COURT: Which are these two videos?

MR. SPECTER: St. Hilaire, and Dr. Lucente.

THE COURT: Any objections that have to be ruled on?

MS. ISMAIL: I don't believe so, Your Honor. The one issue, for the record, in Chambers you had asked us if there is a, if I

can paraphrase, rule of proportionality as to our counters, we have extensive counter designation. That's true for Dr. Lucente. We have agreed with Plaintiff's counsel that we will hold that examination for our case in chief if we so choose. There was a very short counter that we had proposed to the subject matter that the Plaintiffs wanted to play, it looks like we are not going to be able to work that out technically, that we don't have the ability to play your -- there was a couple of questions that we wanted to ask on the compensation issue, which is what counsel is playing the deposition for. If we could play that in completeness, there is a one-minute designation, and then reserve for the balance of our examination for our case in chief is what we are asking.

MR. SLATER: We had a written agreement last week on what we were going to play. They asked us today, we couldn't cut it, we don't want to now change the video, we have a written agreement.

THE COURT: Fine, you can read it to

the jury after the video is finished.

MS. ISMAIL: We will talk over the break.

THE COURT: If you wish not to read it to the jury after the video is finished, you won't read it to the jury after the video is finished.

MS. ISMAIL: Yes, Your Honor.

THE COURT: What else? How about after this 20 minutes? Dr. Zipper is here and available?

MR. SPECTER: Yes, he is.

THE COURT: Well, then maybe we can at least get the credentials out of the way for Dr. Zipper.

Do you have any motions for Dr. Zipper?

MS. ISMAIL: Your Honor, we did have a motion for Dr. Zipper. There was one issue on qualifications I expect isn't going to be the subject of his testimony and he is going to be called only on --

MR. SPECTER: Yes, that's true.

MS. ISMAIL: No, no, that's not -- my question was going to be on that he is really

being called on case-specific bases. We had a question on qualifications to any opinions the witness intends to offer on biomaterials, which is a scientific specialty that this witness is not qualified.

THE COURT: Are you going to present any opinion testimony on biomaterials?

MR. SPECTER: Your Honor, Dr. Zipper is being proffered as an expert in urogynecology, in pelvic floor reconstructive surgery, in vaginal mesh materials, and in the Prolift. Depending upon how one defines the term "biomaterials," I am not quite sure how counsel is thinking about that term, there could be an overlap with vaginal mesh materials, I am not sure. I am not sure what he is thinking about.

THE COURT: Okay. So where are we?

MS. ISMAIL: I am not sure how to interpret counsel's answer.

THE COURT: Okay, he is asking what you mean by biomaterial testimony. Are you able to define it?

MS. ISMAIL: Yes, so the --

THE COURT: Does his report say anything about biomaterials?

MS. ISMAIL: It does in part, Your Honor.

THE COURT: Show Mr. Specter the part that it talks about biomaterials. And in the event, Mr. Specter, you are going to cover any of that on direct, and you can see me in chambers on the record.

MS. ISMAIL: Thank you, Your Honor.

(A brief recess is taken.)

- - -

(The following transpired in the robing room with counsel present:)

MS. ISMAIL: Your Honor, I conferred with Mr. Specter and Mr. Specter indicated as to one of our objections that Dr. Zipper will not opine as to degradation of polypropylene mesh, which was one of our concerns, so that's off the table. My question to him is whether he intends to have this witness describe the properties of polypropylene and its effect on the body. I understood from Mr. Specter that's not going to be the focus of his

examination and that if I have particular objections to questions that exceed Dr. Zipper's qualifications I should raise them. I wanted to make sure that was okay with the Court if I stood up and asked for a sidebar --

THE COURT: I would prefer that you stand up and object and then ask for a sidebar.

What is the area that you think might be objectionable? You said it a minute ago?

MS. ISMAIL: The effect of polypropylene.

THE COURT: The effect of polypropylene in the Prolift?

MS. ISMAIL: In the Prolift, which would require him to opine as to the effect of that material in the human body, which we believe --

THE COURT: Do you expect the testimony to go into the area of the effect of the polypropylene which is what the Prolift is made of in the body?

MR. SPECTER: Sure.

THE COURT: So when it exceeds his qualifications you should at that point object and we will be able to deal with it.

MS. ISMAIL: Very well, Your Honor.

THE COURT: Is that it?

MR. SPECTER: Yes.

THE COURT: Perfect, thank you. Tell Charles to bring in the jury. Are we ready with the video, whatever is next?

MR. SPECTER: Yes.

(The following transpired in open court:)

THE COURT: Call your next witness.

MR. SPECTER: Thank you, Your Honor. Your Honor, at this time, as we advised the Court, we have two brief videos for the jury to see, a total of 20 minutes. The first is Price St. Hilaire, who is an Ethicon employee. The second is Dr. Lucente, who we heard about earlier today.

(At this time, the designated portion of the videotaped deposition testimony of Price St. Hilaire is played for the jury.)

THE COURT: Next witness.

MR. SPECTER: Dr. Lucente, Your Honor.

(At this time, the designated portion of the videotaped deposition testimony of Vincent Lucente, MD, is played for the jury.)

THE COURT: Ladies and gentlemen of the jury, we are going to break at this time. I will ask you to return at 9:30 tomorrow morning. Between now and when you return, keep an open mind and don't discuss the case with anyone, including everything one at home. Charles?

(The jury exits the courtroom at 4:35 p.m., and the following transpired in open court:)

THE COURT: Plaintiff, your next witness is Dr. Zipper?

MR. SPECTER: Yes, sir.

THE COURT: And then who?

MR. SPECTER: We are going to have some more video, Your Honor.

THE COURT: Can you tell me who?

MR. SPECTER: If I may consult with Mr. Slater, yes.

THE COURT: Yes.

MR. SLATER: We have Piet Hinoul; Aaron Kirkemo; Charlotte Owens.

THE COURT: Go ahead.

MR. SLATER: Jim Hart; Kimberly Hunsicker; Scott Jones; Bryan Lisa; Paul Parisi; and along with Dr. Zipper, that is certainly more than enough to cover tomorrow.

THE COURT: Okay. Who was asking about Mr. Parisi?

MR. SLATER: Subject to the order in which we play them, we have Dr. Baker, Dr. Klinge, we have Renee Selman, Sheri McCoy, Alex Gorsky, Axel Arnaud -- he will be earlier than last, though, he will not be the last one.

THE COURT: Okay. Who else?

MR. SLATER: David Robinson. We believe that's it, Your Honor.

THE COURT: That's all your case?

MR. SLATER: And Mrs. Hammons.

THE COURT: Are there objections on any of these videos?

MS. ISMAIL: Your Honor, we raised for the Court's attention already the Kirkemo and the Hinoul issue.

THE COURT: Yes, Kirkemo and?

MS. ISMAIL: Hinoul, same issue.

THE COURT: Are there any other issues besides that one? Any other objections that need a ruling on any of these?

MS. ISMAIL: Potentially.

THE COURT: Fair enough.

MS. ISMAIL: Selman, McCoy and Gorsky, but I will look at them again tonight and we will advise the Court.

THE COURT: But that's it? They just haven't been worked out or withdrawn, is that right?

MS. ISMAIL: Yes, Your Honor.

THE COURT: So I am ready to deal with the totality of Kirkemo's deposition and the first questioning of Hinoul's deposition. I will hear from you.

MR. MORIARTY: So, Your Honor, on Kirkemo, it's a designation of approximately four minutes. The sole purpose of this is to get right to the off-color E-mail. There is really no substantive questioning at all, no

registry, it's not an issue in the case at all, it's not covered with other witnesses. We filed Motion in Limine Number nine to preclude things just like off-color E-mails, that was specifically discussed.

THE COURT: That was denied, wasn't it?

MR. MORIARTY: It was denied because --

THE COURT: So why don't we just deal with this.

MR. MORIARTY: This E-mail is four years after the product launch, and it is irrelevant under 402, and it is highly prejudicial under 403.

THE COURT: Plaintiff? Do you wish to be heard?

MR. SLATER: Yes, Your Honor. The testimony around that E-mail by Dr. Kirkemo and Dr. Hinoul directly relates to our punitive damage claims. Under New Jersey law, we have to prove wanton and willful disregard of the rights, the health, the condition of plaintiff, and in this E-mail we see two of the Medical Affairs directors at Ethicon making jokes about mesh-injured women, which

as doctors, especially as medical directors, would be the last thing that anybody would expect them to be doing.

It goes directly to the heart of our punitive claim. And the defense calls them off-color E-mails, I don't know what that means. I know that this is a couple of medical directors making jokes about mesh-injured women, to the point to where Kirkemo actually does a POP-Q calculation of how a woman's vagina would have to be shaped so you could fit a floppy disk into it.

Is it prejudicial to them? Absolutely. It's not unduly prejudicial, and again, it goes directly to the heart of our punitive claims which we need to prove.

THE COURT: I am sorry to hear it goes to the heart of your punitive claims. The objection is sustained. The deposition of Mr. Kirkemo cannot be played, and the portions Mr. Hinoul's deposition that refer to the E-mail cannot be played.

MR. SLATER: It will be edited out, Your Honor.

THE COURT: Great. Is there anything further that we can accomplish this evening?

MR. SPECTER: No, sir.

MS. ISMAIL: No, Your Honor.

THE COURT: Thank you, see you at 9:30 tomorrow morning -- actually, let's do this. Well, what is first? The first one is Selman, right, that there may be objections on. So we can do that while other videos are playing.

MS. ISMAIL: I believe the first witness will be live.

THE COURT: That's right, but even when we get into videos, we still have plenty of time to deal with any objections that may still exist, right?

MS. ISMAIL: I believe so, Your Honor.

THE COURT: Okay. See you tomorrow at 9:30.

- - -

(Hearing is adjourned at 4:43 p.m.)

- - -

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR
OFFICIAL COURT REPORTER
COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR
OFFICIAL COURT REPORTER
COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.